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NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Definitions and General Considerations

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 207, 210, 225, 226, 501, 510, 514, 558]

[Docket No. 77N-0076]

NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Definitions and General Considerations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This document proposes to redefine the articles used in medicated animal feeds. These amendments are proposed because of ambiguities in the terms as currently defined in FDA regulations and the meanings as used in the animal feed and animal drug industries. The proposal would adopt letter designations for the medicated feed articles.

DATES: Written comments to the Hearing Clerk by March 20, 1978.

ADDRESS: Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Robert P. Schmidt, Bureau of Veterinary Medicine (HFV-224), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3390.

SUPPLEMENTARY INFORMATION: A number of the current regulations affecting animal drugs resulted from application of the Federal Food, Drug, and Cosmetic Act, enacted in 1938, as it evolved before the passage of the Animal Drug Amendments of 1968 (Pub. L. 90-399). For example, section 201(g) of the Federal Food, Drug, and Cosmetic Act (21U.S.C. 321(g)), which defines the term "drug", does not distinguish between drugs intended for use in man or other animals, nor does section 201(p) of the act (21 U.S.C. 321(p)), which defines the term "new drug", distinguish between new drugs intended for use in man or other animals. Therefore, before enactment of the Animal Drug Amendments, new drugs intended for both man and other animals were subject to the preclearance provisions of section 505 of the act (21 U.S.C. 355). In 1945, Congress added section 507 to the act (21 U.S.C. 357) requiring the Secretary, pursuant to regulations promulgated by him, to certify batches of drugs composed wholly or partly of any kind of penicillin. This section has been amended several times to include streptomycin, chlortetracycline, bacitracin, chloramphenicol, and their derivatives. Again, no distinction was made in these provisions between the use of these drugs in man or other animals. Under authority granted by section 507 (c) of the act (21 U.S.C. 357(c)), however, the Commissioner of Food and Drugs exempted antibiotics that were added to animal feeds from the certification provisions if the antibiotics were labeled for specific conditions of use that were published in the regulations.

The Food Additives Amendment of 1958 applied to food additives intended for both man or other animals. This amendment added section 201(s) to the act (21 U.S.C. 321(s)), which defines the term "food additive" as any substance the intended use of which results or may reasonable be expected to result, directly, or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. Thus, any drug added to food or feed of an animal was a food additive, and any drug capable of causing residues in the edible products of the food-producing animal was also considered to be a food additive because the residue from such drug would constitute a food additive in the edible products. Such drugs placed on the market following enactment of the Food Additives Amendment of 1958, could not be legally marketed unless a food additive regulation was promulgated providing for the drug's safe use or the drug was generally recognized as safe and, for those approved after October 10, 1962, effective.

Because animal drugs intended for use in animal feeds were subject to the preclearance provisions of three separate sections of the act and three distinct sets of procedural requirements, their administrative and preclearance provisions were overlapping, unduly complex and time consuming. The Animal Drug Amendments of 1968 were enacted to consolidate the various provisions and requirements applicable to animal drugs into one section of the act and to provide a coordinated, simplified procedure for their implementation. Throughout the lengthy proceedings leading to enactment of the Animal Drug Amendments, both the House and Senate reports noted that in many cases the requirements for preclearance of new drugs intended for use in animals were more complex than the preclearance procedures for drugs intended for use in man, and the need for simplification was continually stressed because the procedures then mandated by law led to long delays in the administrative process required for the preclearance of new animal drugs (Refs. 1-6). The Animal Drug Amendments added a new section—section 512 (21 U.S.C. 360b)—to the act, thereby consolidating into one section the various parts of the act that related to new drugs intended for use in animals, including those intended for use in animal feeds. Consequently, section 512 provides for separate, distinct requirements regarding regulation of new animal drugs and animal feeds bearing or containing new animal drugs.

New sections 201(w) and 201(x) of the act (21 U.S.C. 321(w) and 321(x)) were also added, defining the terms new animal drug and animal feed, respectively. For man and animals the definition of new articles of drug are essentially the same; however, the definition of a new animal drug includes antibiotics subject to certification. The definition of a new animal drug focuses on the article intended to affect the structure or function of animals and any components thereof. On the other hand, the definition of animal feed refers to articles that are intended for use as food for animals other than man and that are intended for use as a substantial source of nutrients in the diet. The term animal feed is not limited to a mixture that is intended to be the sole ration of the animal.

One consistent topic that emerges from a review of the legislative history of the Animal Drug Amendments is the intent to facilitate preclearance review of articles that were used in animal feeds (Refs. 1-6). Before passage of the animal drug amendments, an applicant, e.g., a drug company, was required to file a new drug application (NDA) and have the application approved for the drug's use in animals. If the Drug was an antibiotic subject to certification, an antibiotic Form 5 was required instead of an NDA. When the drug was to be administered to the animal through its feed or it left residues in the edible tissues of food-producing animals, a food additive petition was also required. Each required the applicant to demonstrate that the drug was safe when administered in animal feed. After the Drug Amendments of 1962, a demonstration of effectiveness was also required for drugs covered by both sections 505 and 507 of the act.

Medicated animal feeds have been primarily manufactured at commercial feed mills. These feeds contain animal drugs intended for prevention, cure, mitigation, or treatment of disease (therapeutic use) or intended to affect the structure or function of the animal (growth promotant and feed efficacy). Before enactment of the Animal Drug Amendments, each feed mill manufacturing a medicated feed was required to file an NDA containing authorization from the sponsor to refer to that basic NDA. For drugs covered by section 507 of the act the requirement that a Form 6 be filed

was waived under the provisions of that section. Feed mills that manufacture the finished feed constitute the final step in the commercial distribution of the drug product. Accordingly, the drug company holding an approved NDA for the new drug would authorize feed mills to incorporate the drug's basic safety and effectiveness data into the feed mill's NDA to facilitate manufacture of the medicated animal feed. Because this was an incorporation by reference of the data previously found to be satisfactory by the agency, the basic application was not normally reevaluated for each medicated feed application. Nevertheless, the overlapping statutory requirements and regulations added confusion and delay to the evaluation process without contributing to consumer protection or otherwise improving upon the conditions of the safe and effective use of the drug. For this reason. Congress amended the Federal Food, Drug, and Cosmetic Act in 1968 to differentiate between new animal drugs that are intended for use in a manner that is analogous to the use of drugs in humans, which are regulated solely as drugs, and new animal drugs intended for addition to animal feeds and in effect reformulated by feed mills, which are regulated as both drugs and food additives.

The congressional intent appears to have been to develop a new, separate, expeditious mechanism for reviewing and regulating animal drugs, particularly those used in medicated animal feeds. The history of the Animal Drug Amendments sets forth how this procedure is to function. Initially, a drug company is required to demonstrate, via adequate and well-controlled investigations, that the finished medicated feed article is safe and effective for use in animals. When a new animal drug application (NADA) for this use fo a new animal drug is approved, a regulation reflecting that approval is published in the FEDERAL REGISTER. The manufacture of the medicated feed is then regulated by use of the medicated feed application as provided under the provisions of section 512(m) of the act (21 U.S.C. 360b(m)). This regulatory machanism is analagous to the approach developed for regulating food additives, color additives, and certifiable antibiotics. Perhaps the most difficult task in effectively regulating the medicated animal feed industry, however, is identifying when an article is a medicated animal feed covered by sections 512 (b) and (m) of the act as opposed to an animal drug covered solely by section 512(b) of the act. The dividing line is difficult to establish, but the legislative history provides guidance. This indicates that Congress was concerned primarily with expediting the administrative process of approval without peopardizing the statutory safety requirements.

The Senate report (Ref. 1) identifies the most concentrated medicated animal feed as an article that must be diluted in a ratio of 1 to 100 per ton in an animal feed for safe use. This is defined in the regulations (21 CFR 558.2(b)(4)) as a feed premix. A premix is subject to the requirements of section 512(b) of the act, and thus requires an approved NADA before it can be subsequently remanufactured into what 21 CFR 558.3 (b) (1) through (3) defines as complete feed, feed supplements, and feed concentrates. These definitions were promulgated by the Commissioner in the FEDERAL REGISTER of July 29, 1964 (29 FR 10506), under section 409 of the act (21 U.S.C. 348), and they represent an attempt to facilitate the preclearance of these articles. Moreover, they established the various types of food additives and animal feed products that were applicable to the use of drugs in animal feeds. The terms were defined on the basis of safety considerations such as the concentration of the drug in each article, the intended use of that article, and the risk of harm associated with ingesting the article by the animal for food derived from the animal. The terms also represented what the agency believed to be the current state of the industry. Since 1964, the use of medicated animal feed and the nature of the animal drug industries have changed substantially, as have the types of additives now used, and thus the regulations no longer reflect the terms currently used for these additives in actual practice. Furthermore, ambiguities exist in these terms as defined in 21 CFR 558.3 and the meanings as used in the animal feed and animal drug industries. For these reasons the Commissioner is proposing to redefine the articles used in medicated animal feeds.

I. BASIS FOR PROPOSED ACTION

Section 558.3 (21 CFR 558.3) lists and defines the feed additive articles as complete feed, feed supplement, feed concentrate, and feed premix. Ambiguities have arisen because these commonly used terms have different meanings in the animal health field. To the animal scientist and many others in the industry, a "concentrate" is a concentrated source of energy, e.g., certain basal feedstuffs such as corn, soybeans, or milo. On the other hand, many in the feed industry, animal drug industry, and the regulatory agencies use the term "concentrate" to mean a concentrated is also known as an intermediate premix or custom premix containing only drugs, vitamins, and minerals. Thus, a concentrate for feed may be referred to by several terms, some of which have different meanings.

Similarly, a supplement is known by many in the agricultural industry as an article of feed that supplies protein, vitamins, or minerals to animal diets. These diets are otherwise nutritionally complete. Others view a supplement as being a dilute medicated feed concentrate. The term may also be used to refer to a supplemental medicated feed application.

A premix refers to a concentrated mix of any ingredient normally added to animal feed. It thus includes drugs, nutrients, and other substances. They are added for medicinal or nutritional purposes.

In addition to the practical difficulties arising from the various interpretations of terms, these terms are no longer consistent with the current industry practice, which complicates communication and regulation in the area. New forms of medicated feed articles, such as liquid feeds and blocks, have been developed since the original definitions were established; moreover, the industry has expanded, making different types of drugs and using different manufacturing procedures in larger and more complex feed mills. As a result, different ingredients and equipment are being used to manufacture medicated feed articles, with different intermediate concentrations of drugs. Because the industry has grown exensively, Food and Drug Administration has had to increase the regulatory resources in the medicated animal feed area. This has occurred while severe strains are being imposed on the agency's available resources. To improve the regulation of medicated animal feeds within available resources, the Commissioner is proposing to redefine the various types of medicated feed articles to conform to the current state of the art and to more clearly identify when a medicated feed article requires an approved NADA or an approved medicated feed application. When the original terms in 21 CFR 558.3 were promulgated, the American Feed Manufacturers Association (AFMA) suggested that the medicated feed articles be designated by letter. The commissioner has concluded that new terms are now necessary and that the nomenclature proposed by AFMA provides a practical system for clearly denominating the various types of medicated animal feeds. Thus, the Commissioner is proposing to designate the currently used medicated feed articles as Type A, Type B, Type C, or Type D medicated feed articles, depending upon the concentration of the drug in the article, its intended use, and its nutritional content.

II. PROPOSED DEFINITIONS

A. *Type A medicated feed article.* Under the proposed new definitions, the most concentrated article will be designated as Type A. This is a true drug premix for medicating animal

feed. The article will be solely for use in the manufacture of other medicated animal feed articles (animal feed bearing or containing a new animal drug), and it will, of course, be limited to use solely in accordance with its approved labeling. It will consist principally of a new animal drug in a diluent (carrier substance), and it must be further diluted with nutrient material to produce either a Type B, C, or D medicated feed article.

A proposed Type A medicated feed article is comparable to the present "feed additive premix." In the current regulations, a "premix" must be diluted so that not more than 100 pounds of the article is added to a basic feed to produce one ton of a medicated animal feed, and this feed must have been shown to be safe and effective in accordance with section 512(b) of the act for its labeled drug use. In such premixes, a large quantity of carrier substances is required. The premix is then mixed with basic nutrient feed(s) to produce the medicated animal feed. It is, however, no longer economically feasible to manufacture a premix that requires a large volume of carrier, for example, 90 to 95 pounds of calcium carbonate. A premix that is more concentrated and compact results in savings to users through reduced handling and storage costs. Currently manufactured drug premixes are more concentrated, requiring greater dilution. Today, seldom more than 1 to 5 pounds of premix are required to be added per ton of the nutrient ingredient to produce a finished feed.

The proposed definition of a Type A medicated feed article and the requirements for approval of its NADA have been develop to cover the regulatory problems that may arise from this current trend in the medicated feed industry. Accordingly, the Commissioner has concluded that the requirements being proposed are necessary to assure that the use of a Type A medicated feed article will be restricted to those conditions for which evidence has been submitted showing that the new animal drug is safe and effective as used in its final concentration in Types C and D medicated feed articles intended for use in finished feeds whether manufactured directly or through a Type B article.

The NADA for a Type A medicated feed article must include evidence that all Type B, C, and D medicated feed articles manufactured from it, whether directly or through a Type B article, are safe when used as directed. In addition, the NADA must include adequate and well-controlled investigations demonstrating that such Type C and D medicated feed articles are effective whether manufactured directly or through a Type B article. The NADA must also include manufacturing and stability data of the feed components and the finished feed itself. This information is required for all new animal drugs under section 512(b) of the act. Finally, the NADA must include representative labeling for all articles manufactured from the Type A article.

When the Type A article and the other medicated feed articles (Types B, C, and D) manufactured from it have been shown to be safe and effective under their labeled conditions of use in accordance with the requirements of section 512 of the act and the applicable regulations, the NADA will be approved. Notice of the approval and any applicable restrictions and conditions of use will be published in the FEDERAL REGISTER in accordance with section 512(i) of the act (21 U.S.C. 360b(i)). Consequently, a Type A medicated feed article requires an approved NADA and must be shipped in accordance with section 512(a)(1) of the act and 21 CFR 510.7.

B. *Type B medicated feed article.* The proposed Type B medicated feed article will be an animal feed bearing or containing a new animal drug that is intended for further manufacturing of other medicated feed articles (other B's, C's, or D's) only. The article will consist of a new animal drug(s) approved under section 512 (b) as a Type A medicated feed article, a carrier, and essential nutrients that are intended for nutritional use in subsequently manufactured medicated feed articles. A proposed Type B medicated feed article will conform to the statutory definition of animal feed because it contains substantial source of nutrients and is intended for use as such in an animal's diet. Before the article can be used in the feed of animals, however, it must be substantially diluted with a nutrient substance to form a Type C or D medicated feed article. The determinant for differentiating between the Type B and the other medicated feed articles will be the maximum amount of the Type B medicated feed article that may be added per ton of animal feed to produce a safe and effective Type C or D medicated feed article. This is a direct function of the concentration of the new animal drug and the essential nutrients in the Type B medicated feed article and the potential for that drug to produce unsafe (above tolerance) residues if the article is inadvertently fed to animals. There is no absolute weight limit on these articles because each has specific residue-producing characteristics, and these safety characteristics and any other proposed weight limits are specifically assessed in the NADA approval process in reviewing the Type A medicated feed article. These limitations are then published in 21 CFR Part 558 as special consideration for use of the Type A medicated feed article. In addition to being diluted to a Type C or D article, a Type B medicated feed article containing a new animal drug and essential nutrients can be further diluted to yield another Type B article that may contain an additional new animal drug approved as a Type A or Type B medicated feed article, or other essential nutrients. Again, the concentration of the new animal drug(s) and the ability of that article to produce unsafe residues will be the basis for establishing the distinction between Type B and Types C and D articles.

The NADA for the Type A medicated feed article must contain evidence showing that the finished medicated feed articles produced therefrom are safe and effective. If some vitamins, minerals, or other essential nutrients in the Type B article are intended for use as a drug in the animal feed, the NADA for the Type A article from which it is manufactured must contain evidence showing that the finished feeds satisfy the combination animal drug policy in § 514.1(b)(8)(v) (21 CFR 514.1(b)(8)(v)), i.e., the combination is more effective than the individual ingredients used alone.

The Type B medicated feed article will be similar to the present "feed concentrate." The definition of the Type B article, however, has been revised to encompass intermediate premixes. Intermediate premixes are manufactured by adding essential nutrients to new animal drug premixes. Many manufacturers contend that these intermediate premixes are not new animal drugs since with the addition of the essential nutrients these articles satisfy the statutory definition of animal feed. Because these manufacturers of intermidiate premixes do not make finished medicated feeds, they contend that they are not required to file medicated feed applications. The mechanism that will be established by this proposal to regulate those ostensibly hybrid articles will expand the agency's ability to monitor and regulate these manufacturers.

The agency's primary regulatory concern in the medicated animal feed area is the assurance that human food derived from animals fed medicated animal feed is safe. In the field, the resources available to monitor animal feeds are principally directed at the feed mills that manufacture finished medicated feeds. For this reason, manufacturers of the intermediate premixes have been able to avoid extensive regulatory scrutiny. These proposed revised definitions will bring the manufacturers of these articles to the direct attention of the agency and facilitate application of the current regulatory programs to them. This will also aid the regulatory effort against the manufacture of these articles during a time of limited availability of agency resources. Because a Type B

medicated feed article by definition will contain both new animal drugs and essential nutrients, it will comply with the statutory definition of animal feed. Manufacturers of these articles now have specific notice that they must file a medicated feed application (Form FD-1800) for each such article. In the medicated feed application, the manufacturer must cite the regulation under section 5123(i) of the act and other evidence that establishes the safety and effectiveness of the article before the application can be approved.

The basic medicated feed application will concurrently be amended to reflect the agency's revised program concerning manufacturers of the Type B articles. The current application requires the following basic information:

1. Name and address of the applicant;

2. The registration number and last date of registration of each mill as assigned pursuant to section 510 of the act;

3. Whether the submission is an original or supplemental application;

4. Identification of the drug(s) or premix used by name, potency, and manufacturer;

5. The species of animal(s) for which the medicated feed is intended;

6. The form of feed to be produced, i.e., mash, meal, crumbles, pellets, liquid, or other;

7. Whether the feed is to be packaged in bag or bulk;

8. Whether the feed is for sale or own use;

9. The brand name of the medicated feed, name of the drug(s) and finished level in feed, and amount of drug(s) or premix per ton;

10. Identification of the regulation(s) found in Part 558 (21 CFR Part 558) and published pursuant to section 512(i) of the act on which the request for approval of the medicated feed is based;

11. Whether the attached labeling is in draft or final printed form;

12. A statement of minimum and maximum assay permitted from the labeled amount of the drug;

13. If the application provides for manufacture of a medicated feed bearing or containing a new animal drug subject to the certification provisions of section 512(n) of the act, the appropriate fee as set forth in 21 CFR 514.60;

14. Identification of the authorized agent;

15. Applicant's name, title, and signature of responsible individual, and date.

Type B medicated feed articles will be limited to further manufacturing purposes only and will contain concentrated new animal drugs and essential nutrients. The latter includes vitamins and minerals in addition to other essential nutrients. Such ingredients must be covered either by a GRAS regulation, a food additive regulation, or if intended for therapeutic use, by an approved NADA. Because the article will have very concentrated levels of active ingredients, it is necessary to increase the assurance that the articles contain the precisely labeled amount of the new animal drug and essential nutrients. Only a minor deviation from the required content may result in considerable variations of concentration in medicated feed articles that are manufactured from the Type B articles. For this reason, random assays must be conducted more frequently for Type B articles than for other, less concentrated medicated feed articles (Types C and D). The medicated feed application for the manufacture of a Type B medicated feed article, therefore, must also contain the following additional information:

1. The master or batch formula used in the manufacture of the Type B medicated feed article. The batch formula shall provide for use of only recognized or approved feed ingredients;

2. Appropriate labeling providing adequate directions for the manufacture and use of other Type B, C, and/or D medicated feed articles;

3. A description of manufacturing facilities, including mixing time, equipment used, and the personnel responsible for the manufacturing operations;

4. Identification of any lot or batch numbering system used in the manufacturing, processing, packaging, and labeling of the Type B medicated feed article;

5. A commitment to perform representative assays, with results of assay being within the established assay limit, on the first three batches of the Type B article manufactured, additional samplings to be assayed at random intervals representing 5 percent of the annual production of each Type B medicated feed article covered by the application. The reports of assay shall be kept on the premises for not less than 1 year after the date of shipment of the medicated feed.

The applicable regulations will be amended accordingly.

When the medicated feed application is approved for a Type B medicated feed article, the holder of that approved application must then comply with the other requirements imposed by the statute and regulations. Manufacturers of Type B articles may sell them only in conformance with section 512(a)(1) of the Act and 21 CFR Part 558. Finally, the new animal drugs in the articles are covered by approved NADA's, which contain evidence demonstrating their safety and effectiveness; and the primary problems associated with intermediate premixes are independent of the questions about basic safety and effectiveness. The problems concern the ability to assure that these articles are properly formulated and manufactured to maintain their purity, stability, and potency so as to be safe and effective when formulated into finished medicated animal feed as directed by the approved labeling. On that basis, the Commissioner is proposing to redefine types of ingredients used in medicated animal feeds to regulate intermediate premixes as Type B medicated feed articles under section 512(m) of the act rather than section 512(b).

Because this is merely a proposal that will be subject to public comment and potential revision, the exact terms of the final order cannot be forecast; therefore, the Commissioner concludes that current policy for intermediate premixes should continue: Intermediate premixes are subject to the provisions of section 512(b) of the act. The manufacturers of intermediate premixes containing certain antibacterials were exempted from the requirement for filing an NADA and certain data under §558.15 (21 CFR 558.15); however, the Commissioner will prepare proposals to deal separately with those articles as he concludes the Antibiotics in Animal Feeds Program. Moreover, to assure an orderly transition period, the Commissioner will outline an implementation program for filing the appropriate applications for Type B medicated feed articles in the final order. Tentatively, he anticipates permitting a period of 90 days, following the promulgation of the final order, for the submission of the appropriate medicated feed applications for the manufacture of the Type B medicated feed article, unless it is determined that the Type B medicated feed article is not required to comply with the provisions of section 512(m) of the act. Under section 512(m)(2) of the act, the agency then has 90 days to review and approve, if appropriate, that application. This is essentially a 180-day implementation period. The Commissioner will then also provide a similar implementation period for filing and approving the appropriate applications for the manufacture of Types C and D medicated feed articles from Type B articles.

C. *Type C medicated feed article.* A proposed Type C medicated feed article is also a medicated animal feed bearing or containing a new animal drug. It will be produced by substantially diluting a Type A or Type B medicated feed article with other feed ingredients to a level for a use that is covered by an approved NADA. A Type C article may have two intended uses. It may be further diluted or mixed to produce Type D medicated feed articles, i.e., a complete feed; or it may be fed top dressed, undiluted, or

offered free-choice in conjunction with other animal feed to supplement the animal's total daily ration. The Type C article does not contain the animal's complete source of nutrients. When a proposed Type C article is fed undiluted, or offered free-choice in amounts not less than one-half pound per head per day and with other parts of the ration separately available, e.g., when spread over silage, the article shall not produce residues in food from food-producing animals that are unsafe within the meaning of section 512 of the act. This article is similar to the current "feed supplement," and the manufacture of Type C articles will require a medicated feed application approved under section 512(m) of the act unless otherwise specified, and the use of the new animal drug must be covered by a regulation published in 21 CFR Part 558. Any use approved prior to the effective date of these revised definitions providing for administration of less than one-half pound per head per day must be the subject of a supplemental application revising the conditions of use to conform to the definition of the Type C medicated feed article.

D. *Type D medicated feed article.* A Type D medicated feed article will be essentially identical to the current "complete feed." It will be for administration as the sole ration to an animal. Therefore, Type D medicated feed articles will contain the animal's total supply of essential nutrients (excluding hay and water) in addition to the new animal drug. Type D articles will be manufactured by diluting Types A, B, or C medicated feed articles with basic animal feed to provide the animal feed to provide the animal with its complete ration. The manufacture of Type D articles will require approval of a medicated feed application under section 512(m) of the act (21 U.S.C. 360b(m)), unless otherwise specified, and use of the new animal drug in the finished feed must be covered by a regulation published in 21 CFR Part 558.

III. Production Classes and Definitions

The Commissioner is also proposing to redefine terms pertaining to the various production classes of animals in the livestock and poultry industries. These industries also have vastly expanded over the past decade as they have developed sophisticated techniques for growing animals faster and more efficiently. The classes listed in 21 CRF 558.3 do not include many of the now common production classes of poultry, swine, and cattle, nor are definitions of the terms consistent with the contemporary meanings. New animal drug applications are filed and approved with labeling directed at the contemporary livestock practies. For this reason, the Commissioner is proposing to revise the terms and definitions to conform with current livestock and poultry practice (Refs. 7-9).

V. Conforming Amendments

Revising the definitions of medicated feed articles and production classes of animals has a substantial impact on numerous other regulations in the new animal drug area. Those affected regulations must be amended to permit rational effective regulation in this area.

A. *Section 501.110 Animal feed labeling; collective names for feed ingredients (21 CFR 501.110).* The section, promulgated under section 402(i)(2) of the act (21 U.S.C. 342(i)(2)), permits the use of collective names for feed ingredients in lieu of listing each feed ingredient by its common or usual name and in decreasing order of predominance as required by 21 CFR 501.4. The regulation was promulgated for the convenience of the parties involved and in recognition of the terms of the art used by industry. At present, § 501.110 exempts all animal feed intended solely for use in livestock and poultry from the requirements of § 501.4 when the feed conforms to other criteria as set forth in § 501.110. A proposed Type B medicated feed article may be used only for the manufacture of other Type B, or C, or D articles. The Commissioner has found, however, that full ingredient information on the compostion of the Type B articles is necessary for the manufacturers of Type B, C, and D medicated feet articles. He is proposing to amend the regulation to require that Type B articles list all ingredients by their common or usual name in decreasing order of predominance as required by § 501.4.

B. *Prior registration.* Under 21 CFR 207.20(c), manufacturers of both new animal drugs and medicated animal feeds must register pursuant to section 510 of the act (21 U.S.C. 360), and the registration is required prior to approval of any NADA's or medicated feed applications. Currently, only manufacturers of new animal drugs and premixes are required to submit a list of the drugs they commercially distribute under 21 CFR 207.20(a); manufacturers of medicated animal feeds are exempt from this requirement by section 510(g)(4) of the act (21 U.S.C. 360(g)(4)). Under the new proposed definitions, the information currently made available through drug listing will no longer be required for Type B articles because they will be medicated animal feeds, but the identical information previously obtained through drug listing will be available through the submission of a medicated feed application (Form FD-1800).

C. *Assays.* The laboratory control section of the current good manufacturing practice regulations for medicated animal feeds (21 CFR 225.58) requires periodic assays for drug content of the medicated animal feeds being manufactured at each feed mill. This was in lieu of the assay requirements that the Commissioner concludes are necessary for assuring the safe manufacture of Type B medicated feed articles. Therefore, the Commissioner is proposing to amend this section to require a more rigorous assay schedule for manufacturers of Type B articles than required for type C and D articles.

D. *Applications.* In 21 CFR 514.1, the formal procedures for filing an NADA under section 512(b) of the act are prescribed. The Commissioner is proposing to amend § 514.1 to require that the applicant file all information necessary to determine that a medicated feed article is to be manufactured from a new animal drug covered by an approved NADA and that it will be safe and effective. For this reason, an NADA for a Type A medicated feed article must include representative labeling of medicated feed articles intended to be produced from it. Therefore, he proposes to amend § 514.1(b)(3)(v)(*b*) accordingly.

In addition, a Type B medicated feed article may contain nutrients from a number of sources of concentrated protein, vitamins, and minerals. Because of the possible interactions among the added ingredients and between these ingredients and the new animal drug, the Commissioner has concluded that the stability of the drug must be established in representative formulations of Type B medicated feed articles. Therefore, the Commissioner is also proposing to amend § 514.1(b)(5)(x) to require that the NADA include data or commitments to provide stability data covering representative formulations of Type B, C, and D medicated feed articles.

E. *Return of applications.* Section 558.4 (21 CFR 558.4) provides that medicated feed applications will be returned by the agency, i.e., the Bureau of Veterinary Medicine, without review if there is no regulation established in Part 558 that would provide a basis for its approval. The Commissioner is proposing a new section, § 514.112 *Return of applications for animal feeds bearing or containing new animal drugs,* which incorporates the provisions of the current § 558.4 *Approval of new animal drug applications for medicated feeds.*

F. *New feed terms.* All new animal drugs approved for use in animal feeds are codified in Subpart B of 21 CFR Part 558. The proposed definitions of medicated feed articles will require revision of the regulations to reflect the use of the new feed terms. The commissioner is proposing to amend this subpart accordingly.

The Commissioner has carefully considered the environmental effects

of the proposed regulation and because the proposed action would not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the FDA environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

REFERENCES

1. Senate Committee on Labor and Public Welfare, Animal Drug Amendments of 1968, S. Rep. No. 1308, 90th Cong., 2d Sess. (1968).
2. Hearings on H.R. 7655 et al. Before The Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 89th Cong., 2d Sess., Ser. No. 89-36 (1966).
3. House Committee on Interstate and Foreign Commerce, Animal Drug Amendments of 1966, H.R. Rep. No. 2168, 89th Cong., 2d Sess. (1966).
4. Hearings on H.R. 3639 Before the Subcommittee on Public Health and Welfare of the House Comm. on Interstate and Foreign Commerce, 90th Cong., 1st Sess., Ser. No. 90-12 (1967).
5. House Committee on Interstate and Foreign Commerce. Animal Drug Amendments of 1967, H.R. Rep. No. 875, 90th Cong., 1st Sess. (1967).
6. Hearing on S. 1600 and H.R. 3639 Before the Subcommittee on Health of the Senate Comm. on Labor and Public Welfare, 90th Cong., 2d Sess. (1968).
7. Ensminger, M. E., "The Stockman's Handbook," Interstate Printers and Publishers, Inc., 3d Ed., 1965,
8. Carl, L. E., "Poultry Production," 10th Ed., 1966.
9. Marsden, S., "Turkey Production," USDA Handbook No. 393 (1971).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Parts 207, 210, 225, 501, 510, 514, and 558 be amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

§ 207.20 [Amended]

1. Section 207.20 *Who must register and submit a drug list* is amended in paragraph (a) by revising the text in the last parenthetical statement to read "(including a Type B, C, or D medicated feed article as defined in § 558.3 of this chapter)".

PART 210—CURRENT GOOD MANUFACTURING PRACTICES IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS: GENERAL

2. In § 210.3, paragraphs (c) (1) and (2) are revised to read as follows:

§ 210.3 Definitions.

* * * * *

(c) * * *

(1) The term "medicated feed" means any Type B, C, or D medicated feed article as defined in § 558.3 of this chapter. The feed contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated feeds is subject to the requirements of Part 225 of this chapter.

(2) The term "medicated premix" means a Type A medicated feed article as defined in § 558.3 of this chapter. The article contains one or more drugs as defined in section 201(g) of the act. The manufacture of medicated premixes is subject to the requirements of Part 226 of this chapter.

* * * * *

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

3. In § 225.58, by revising the first sentence of both paragraphs (b)(1) and (b)(2), and by adding paragraph (b)(3), to read as follows:

§ 225.58 Laboratory controls.

* * * * *

(b) * * *

(1) For Type C and D medicated feed articles requiring approved Medicated Feed Applications (Form FD-1800) for their manufacture and marketing. * * *

(2) For Type C and D medicated feed articles not requiring approved Medicated Feed Applications (Form FD-1800) for their manufacture and marketing. * * *

(3) For all Type B medicated feed articles, assays of the first three batches manufactured, followed thereafter by assay of random representative samples of not less than 5 percent of the annual production of each batch produced. The samples shall be collected and assayed by approved official methods. When any batch does not assay within limitations, each subsequent batch shall be assayed until five consecutive batches are within limitations. Reports of assay shall be kept on the premises for not less than 1 year after the date of shipment of the medicated feed.

* * * * *

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED PREMIXES

§ 226.58 [Amended]

4. In § 226.58 *Laboratory controls,* by deleting paragraph (c)(2) and designating it "reserved."

PART 501—ANIMAL FOOD LABELING

5. In § 501.110, by revising paragraph (a)(1) to read as follows:

§ 501.110 Animal feed labeling; collective names for feed ingredients.

(a) * * *

(1) The animal feed is a Type C or D medicated feed article as defined in § 558.3 of this chapter and is intended solely for animal use.

* * * * *

PART 510—NEW ANIMAL DRUGS

In § 510.3, by adding new paragraph (m) to read as follows:

§ 510.3 Definitions and interpretations.

* * * * *

(m) The following terms apply to various production classes of animals:

(1) *In poultry* (i) "Broiler chickens" and "fryer chickens" are synonymous and denote chickens marketed for meat purposes only, usually at 6 to 9 weeks of age.

(ii) "Roaster chickens" are chickens marketed for meat purposes only, usually at 9 to 14 weeks of age.

(iii) "Replacement chickens" are chickens being raised for the purpose of replacing egg-producing chickens only.

(iv) "Laying chickens" are chickens producing eggs for food only.

(v) "Breeding chickens" are chickens producing eggs for hatching purposes only.

(vi) "Fryer-roaster turkeys" are turkeys of either sex marketed for meat purposes only, usually at 12 to 17 weeks of age.

(vii) "Young hen or tom turkeys" are turkeys marketed for meat purposes only, usually at 17 to 26 weeks of age.

(viii) "Replacement turkeys" are turkeys being raised for the purpose of replacing breeding turkeys only.

(ix) "Breeding turkeys" are turkeys producing eggs for hatching purposes only.

(2) *In swine.* (i) "Prestarting swine" are swine that weigh between 5 and 10 pounds.

(ii) "Starting swine" are swine that weigh between 11 and 40 pounds.

(iii) "Growing swine" are swine that weigh between 41 and 100 pounds.

(iv) "Finishing Swine" are swine that weigh between 101 pounds and market weight (180 to 250 pounds).

(v) "Growing-finishing swine" is a term that includes the weight ranges of both growing swine and finishing swine.

(vi) "Breeding swine" are swine used for reproductive purposes.

(3) *In ruminants.* (i) "Calves" are young bovine animals that have a live weight of less than 450 pounds and are less than 8 months of age.

(ii) "Cattle" are bovine animals over 8 months of age.

(*a*) "Feedlot cattle" are those that are maintained in feedlots and intended for slaughter.

(*b*) "Breeding cattle" are those that are intended primarily for breeding purposes.

(c) "Lactating dairy cows" are cows of dairy or dual purpose breeds that produce milk that is intended for human consumption.

(d) "Nonlactating or dry dairy cows" are cows of dairy or dual purpose breeds that temporarily are not producing milk.

(iii) "Lambs" are ovine animals from birth to 14 months of age.

(iv) "Breeding sheep" are ovine animals that are intended primarily for breeding purposes.

PART 514—NEW ANIMAL DRUG APPLICATIONS

7. Part 514 is amended:

a. In § 514.1 by revising paragraphs (b)(2)(c)(*b*) and (b)(5)(x) to read as follows:

§ 514.1 Applications.

* * * * *

(b) * * *
(3) * * *
(v) * * *

(*b*) Representative labeling proposed to be used for Type B, C, and D medicated feed articles manufactured from the new animal drug.

* * * * *

(5) * * *

(x) A complete description of, and data derived from, studies of the stability of the new animal drug, including information showing the suitability of the analytical methods used. A description of any additional stability studies underway or planned. Stability data for the finished dosage form of the new animal drug in the container in which it is to be marketed, including any proposed multiple-dose container, and, if it is to be put into solution at the time of dispensing, for the solution prepared as directed. If the new animal drug is intended for use in the manufacture of Type B, C, or D medicated feed articles as defined in § 558.3 of this chapter, stability data shall be derived from studies in which representative formulations of the medicated feed articles are used. These formulations include concentrated proteins, vitamins, and/or minerals. If the data indicate that an expiration date is needed to guarantee the identity, strength, quality, and purity of the new animal drug or Type B medicated feed article, the applicant shall propose such expiration date. If no expiration date is proposed, the applicant shall justify its absence.

* * * * *

b. By revising § 514.2 to read as follows:

§ 514.2 Applications for animal feeds bearing or containing new animal drugs.

(a) Applications to be filed under section 512(m) of the act shall be completed, signed, and submitted in triplicate in the form described in paragraphs (b) and (c) of this section.

(b) Each application for a Type B, C, or D medicated feed article shall be completed to include the following information:

(1) The name and address of the applicant.

(2) The registration number assigned pursuant to section 510 of the act and last date of registration of each mill.

(3) Whether the submission is an original or supplemental application.

(4) Identification of the drug(s) or Type A or B medicated feed article used by name, potency, and manufacturer.

(5) The species of animal(s) for which the feed is intended.

(6) The form of feed to be produced, i.e., mash, meal, crumbles, pellets, liquid, or other specified form.

(7) Whether the feed it to be packaged in bag or bulk.

(8) Whether the feed is for further manufacturing only or for sale or for own use (not for sale).

(9) The brand name of the medicated feed, name and level of the drug(s) in the finished feed, and the amount of Type A or D medicated feed article per ton contained therein.

(10) Identification of the regulation(s) found in Part 558 of this chapter and published pursuant to section 512(i) of the act on which the request for approval of the drug ingredients is based.

(11) The specimen label or labeling, with an indication whether draft or final copy, attached to each copy of the application. This shall consist of bag labels, invoice copy, bulk labels, and placards when applicable.

(12) A commitment to establish and maintain the required program of sampling and assaying to Type C and D medicated feed articles. The program shall include assay of at least three representative samples of medicated feed articles containing each drug or drug combination used in the establishment. These samples shall be collected and assayed by approved official methods at periodic intervals during the calendar year, unless otherwise specified in this chapter. At least one of these assays shall be performed on the first batch using the drug. Additional requirements for Type B medicated feed articles are set forth in paragraph (c)(6) of this section. If a medicated feed article contains a combination of drugs, only one of the drugs needs to be subject to analysis each time, provided the one tested is different from the one(s) previously tested.

(13) A statement of the minimum and maximum assay permitted from the labeled amount of the drug.

(14) A statement of the appropriate fee accompanying the application if it provides for the use of a new animal drug subject to the provisions of section 512(n) of the act as prescribed by § 514.60.

(15) Identification of agent authorized to act on behalf of applicant.

(16) The applicant's name, responsible individual's title and original signature, and date.

(c) If the application requsts approval for the manufacture of a Type B medicated feed article, it shall include in addition to the information required by paragraph (b) of this section, the following:

(1) A full list and quantity of each ingredient, i.e., the master formula.

(2) Appropriate specimen labeling of the article providing adequate directions for the manufacture and use of Type B, C, and/or D medicated feed articles.

(3) A description of the facilities used for the manufacture of the medicated feed article, including the following:

(i) A description of the mixing equipment, including name, type (vertical, horizontal, etc,), and capacity.

(ii) A description of the measuring equipment (scales or other metering devices) used, including the name, type, capacity, and accuracy or smallest graduation.

(4) A statement of the mixing time used to assure uniformity of the medicated feed.

(5) A designation of the person for supervision and control of the mixing operation.

(6) A commitment to establish and maintain the required program of sampling and assay. This program shall be in lieu of that required by paragraph (b) (12) of this section. The program shall consist of assays of the first three batches manufactured, followed thereafter by assay of random representative samples of not less than 5 percent of the annual production of each Type B medicated feed article covered by the application. The samples shall be collected and assayed by approved official methods. When any batch does not assay within limitations, each subsequent batch shall be assayed until five consecutive batches are within limitations. Reports of assay shall be kept on the premises for not less than 1 year after the date of shipment of the medicated feed.

(7) A designation of who will be performing the assays required by paragraph (c)(6) of this section, e.g., whether the assays are to be conducted by the applicant in their own laboratory, or the name and address of a designated laboratory.

(d) Upon approval, one copy of the application will be signed by an authorized employee of the Food and Drug

Administration designated by the Commissioner, and it will be returned to the applicant.

c. By adding new § 514.112 to read as follows:

§ 514.112 Return of applications for animal feeds bearing or containing new animal drugs.

Applications submitted pursuant to § 514.2 will be returned to the applicant if such applications are incomplete or inaccurate or do not contain an identification of the applicable regulation(s). These regulations, published pursuant to section 512(i) of the act, are found in Part 558 of this chapter, and are the basis on which approval of the application relies, as required by § 514.2(b)(10).

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

8. Part 558 is amended:

a. By revising § 558.3 to read as follows:

§ 558.3 Definitions and general considerations applicable to this part.

(a) Regulations established in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross reference. Unless provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) A "Type A medicated feed article" is a new animal drug premix intended solely for use in the manufacture of Type B, C, or D medicated feed articles. It consists of a new animal drug(s), and carrier (e.g., calcium carbonate, rice hull, corn gluten) with or without other inactive ingredients. It must be further diluted before it can be safely administered to animals. Manufacture of a Type A medicated feed article requires an application approved under section 512(b) of the act.

(2) A "Type B medicated feed article" is an animal feed containing a new animal drug(s) and is intended solely for the manufacture of other medicated feed articles (Types B, C, or D), and is not for direct administration to the animal. It is manufactured by substantially diluting either a Type A or another Type B medicated feed article with nutrient ingredients. The Type B article must be further diluted with nutrients to produce either a Type C or Type D medicated feed article. The manufacture of a Type B article must be in accordance with a regulation in Part 558 providing for the use of the drug. Its manufacture must also be the subject of an application approved pursuant to section 512(m) of the act unless a waiver from the requirements of such application is included in the Part 558 regulation providing for the use of the drug.

(3) A "Type C medicated feed article" is an animal feed bearing or containing a new animal drug(s). It is produced by subtantially diluting a Type A or B medicated feed article with other feed ingredients to a use level that is covered by an approved NADA. A Type C article may be further diluted or mixed to produce another Type C medicated feed article or a Type D article, or it may be fed top dressed, on or offered free-choice in conjunction with other animal feed. It does not contain the animal's complete source of nutrients. When a Type C article is fed undiluted or offered free-choice, in amounts to not less than one-half pound per head per day, the article shall not produce residues in food from food-producing animals that are unsafe within the meaning of section 512 of the act. The manufacture of a Type C article must be in accordance with a regulation in Part 558 providing for the use of the drug. Its manufacture must also be the subject of an application approved pursuant to section 512(m) of the act unless a waiver from the requirements of such application is included in the Part 558 regulation providing for the use of the drug.

(4) A "Type D medicated feed article" is a complete animal feed bearing or containing a new animal drug(s) that is produced by diluting Type A, B, or C medicated feed articles with nutrients. It is intended to be fed as the sole ration to an animal, with or without added roughage. The manufacture of a Type D article must be in accordance with a regulation in Part 558 providing for the use of the drug. Its manufacture must also be the subject of an application approved pursuant to section 512(m) of the act unless a waiver from the requirements of such application is included in the Part 558 regulation providing for the use of the drug.

§ 558.4 [Revoked]

b. By revoking § 558.4.

c. By republishing Subpart B of Part 558 to reflect the proposed definitions and other considerations, as follows:

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

AUTHORITY: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).

558.25 2-Acetylamino-5-nitrothiazole.

(a) *Specifications.* Assay of not less than 96 percent by ultraviolet spectrophotometry.

(b) *Approvals.* (1) Type A medicated feed article: 10 percent to No. 010042 in § 510.600(c) of this chapter.

(c) *Related tolerances in edible products.* See § 556.20 of this chapter.

(d) *Conditions of use.* It is used in Type D medicated feed articles for turkeys as follows:

(1) *Amount per ton.* 136.2 grams (0.015 percent).

(i) *Indications for use.* Aid in prevention of blackhead (histomoniasis).

(ii) *Limitations.* Administer continuously starting 1 to 2 weeks before outbreaks usually occur: discontinue use 7 days before slaughter; use eggs from medicated birds for hatching purposes only.

(2) *Amount per ton.* 454 grams (0.05 percent).

(i) *Indications for use.* Aid in control of blackhead (histomoniasis).

(ii) *Limitations.* Administer for 2 weeks at first sign of outbreaks; discontinue use 7 days before slaughter; use eggs from medicated birds for hatching purposes only.

§ 558.35 Aklomide.

(a) *Chemical name.* 2-Chloro-4-nitrobenazmide.

(b) *Specifications.* (1) Minimum melting point 170°C.

(2) Moisture content not to exceed 1 percent.

(3) Purity not less than 98 percent on anhydrous basis.

(c) *Approvals.* Type A medicated feed articles to No. 017210 in § 510.600(c) of this chapter, as follows:

(1) 50 percent aklomide.

(2) 20 percent sulfanitran and 25 percent aklomide.

(3) 25 percent aklomide, 20 percent sulfanitran, and 5 percent roxarsone.

(4) 50 percent aklomide and 10 percent roxarsone.

(d) *Assay limits.* Type D medicated feed article: 85 to 120 percent of labeled amount.

(e) *Special considerations.* Type D medicated feed articles manufactured from Type C medicated feed articles that contain not more than 0.1 percent aklomide and conform to the requirements of this section are not required to comply with the provisions of section 512(m) of the act.

(f) *Related tolerances.* See § 556.30 of this chapter.

(g) *Conditions of use.* It is used in Type D medicated feed articles for chickens as follows:

(1) *Amount per ton.* Aklomide, 227 grams (0.025 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella* and *E. necatrix.*

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption.

(2) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter.

(3) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with

sulfanitran, 181.6 grams (0.02 percent) + roxarsone, 22.7-45.4 grams (0.0025-0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(ii) Limitations. Not to be fed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

(4) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with roxarsone, 22.7-45.4 grams (0.0025-0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tennella,* and *E. necatrix;* growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

§ 558.45 Ammonium chloride, feed grade.

(a) *Chemical name.* Ammonium chloride.

(b) *Specifications.* The ammonium chloride conforms to the following:

(1) Assay after drying: 99 percent minimum.

(2) Sodium chloride: 0.6 percent maximum.

(3) Loss on drying: 0.5 percent maximum.

(4) Arsenic (as AS): 3 parts per million maximum.

(5) Heavy metals (as Pb): 10 parts per million maximum.

(c) *Approvals.* Type A medicated feed articles: 99 percent, see Nos. 011462 and 000018 in § 510.600(c) of this chapter.

(d) *Assay limits.* Type D medicated feed articles: 85 to 115 percent of labeled amount.

(e) *Special considerations.* Maximum level permitted in a Type C medicated feed article is 8 percent for administration to cattle and 6 percent for administration to sheep.

(f) *Conditions of use.* It is used in Type C or D medicated feed article for cattle and sheep as follows:

(1) *Amount per day.* 21.3-35.5 grams (0.75-1.25 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For range cattle.

(2) *Amount per day.* 28.4-42.5 grams (1.0-1.5 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For fattening cattle.

(3) *Amount per day.* 7.1 grams (0.25 oz.) per head.

(i) *Indications for use.* Reduction of the incidence of urinary calculi.

(ii) *Limitations.* For sheep.

§ 558.55 Amprolium.

(a) *Approvals.* (1) Type A medicated feed article: 25 percent to No. 000006 in § 510.600(c) of this chapter for use as in paragraph (e)(1) of this section.

(2) [Reserved]

(b) *Assay limits.* Type D medicated feed articles: 80 to 120 percent of labeled amount.

(c) *Special considerations.* (1) Do not use in Type B, C, or D articles containing bentonite.

(2) Type D medicated feed articles containing amprolium as the sole drug, processed from Type C medicated feed articles containing not more than 0.05 percent amprolium, and conforming to the requirements of paragraph (e) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.50 of this chapter.

(e) *Conditions of use*—(1) *Calves.* It is used in Type C or D medicated feed articles as follows:

(*i*) *Amount.* 227 milligrams per 100 pounds (5 milligrams per kilogram) body weight per day.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(*b*) *Limitations.* Administer from a Type C medicated feed article containing from 0.05 to 0.5 percent amprolium with the usual amount of feed consumed in 1 day; feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter; as sole source of amprolium.

(*ii*) *Amount.* 454 miligrams per 100 points (10 milligrams per kilogram) body weight per day.

(*ii*) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii.*

(*b*) *Limitations.* Administer from a Type C medicated feed article containing from 0.05 to 0.5 percent amprolium with the usual amount of feed consumed in 1 day; feed for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter; as sole source of amprolium.

(2) *Chickens and turkeys.* It is used in Type D medicated feed articles as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004 pct. to 0.0125 pct.).	.....	Replacement chickens; development of active immunity to coccidiosis.	Feed as follows	.....

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium grams per ton	*Amprolium grams per ton*	*Amprolium grams per ton*
Severe exposure to coccidiosis.	113.5 (0.0125 pct).	72.6-113.5 (0.008 pct to 0.0125 pct).	36.3-113.5 (0.004 pct to 0.0125 pct)
Moderate exposure to coccidiosis.	72.6-113.5 (0.008 pct to 0.0125 pct).	54.5-113.5 (0.006 pct to 0.0125 pct).	36.3-113.5 (0.004 pct to 0.0125 pct)
Slight exposure to coccidiosis.	36.3-113.5 (0.004 pct to 0.0125 pct).	36.3-113.5 (0.004 pct to 0.0125 pct).	36.3-113.5 (0.004 pct to 0.0125 pct)

Arsanilate sodium 90 (0.01 pct).	Replacement chickens: development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	.....
Arsanilic acid 90 (0.01 pct).	do	do	.....

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	do	do	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 92.5.	1. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
		2. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 185.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Bacitracin 100 to 200	Replacement chickens; development of active immunity to coccidiosis; treatmentof chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate or bacitracin zinc. Feed according to subtable in item (i).	
	Chlortetracycline 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis..	Not to be fed to laying chickens; as chlortetracycline hydrochloride. Feed according to subtable in item (i).	
	Erythromycin 4.6 to 18.5.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.	As erythromycin thiocyanate. Feed according to subtable in item (i).	
	Erythromycin 92.5....	1. Replacement chickens; developmnt of active immunity to coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 24 h before slaughter. Feed according to subtable in item (i).	
		2. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter. Feed according to subtable in item (i).	
	Erythromycin 185.....	Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter. Feed according to subtable in item (i).	
	Hygromycin B 8 to 12.	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms (*Ascaris Galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	Feed according to subtable in item (i)	
	Penicillin 2.4 to 50....	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.	As procaine penicillin. Food according to subtable in item (i).	
	Penicillin plus streptomycin 90 to 180 (of combination).	Replacement chickens; development of active immunity to coccidiosis; treatmentof chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis)..	Type D article contains 16.7% penicillin; as procaine penicillin; as streptomycin sulfate. Feed according to subtable in item (i).	
	Roxarsone 22.7 to 45.4 (0.0025 to 0.005 pct).	Replacement chickens; development of active immunity to coccidiosis; growth promotion, and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
(ii) 72.6 to 113.5 (0.008 pct to 0.0125 pct).	.....	Broiler chickens; prevention of coccidiosis caused by *Eimeria tenella* only.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Arsanilate sodium 90 (0.01 pct).	Broiler chickens prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01 pct).	do	do	
	Bacitracin 100 to 200	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate, or zinc bacitracin	
	Chlortetracycline 100 to 200.	Broiler chickens; prevention of coccidiosis caused by *E. Tenella* only; treatmentof chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.	Not for laying chickens; as chlortetracycline hydrochloride.	
	Hygromycin B 8 to 12.	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; control of infestations of large roundworms (*Heterakis gallinae*), and capillary worms (*Capilluria obsignata*).	Feed according to subtable in item (ii)	
	Penicillin 2.4 to 50....	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency.	As procaine penicillin	
	Penicillin plus streptomycin 90 to 180 (of combination).	Treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	Type D article contains 16.7 pct penicillin; as procaine penicillin; as streptomycin sulfate.	
	Roxarsone 22.7 to 45.4 (0.0025 to 0.005 pct).	Broiler chickens; prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) 113.5 (0.0125 pct).	.....	1. Laying chickens; prevention of coccidiosis.....	.....	.....
		2. Laying chickens; treatment of coccidiosis.....	For moderate outbreaks of coccidiosis; administer for 2 weeks.	.....
	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025 to 0.00375 pct).	Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency and improved pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; roxarsone as provided by No. 07210 in sec. 510.600 (c) of this chapter, bambermycins by No. 000039; withdraw 5 d before slaughter..	.....
(iv) 113.5 to 227 (0.0125 to 0.025 pct).	.....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	.....	.....
		2. Turkeys; prevention of coccidiosis.....	.....	.....
	Arsanilate sodium 90 (0.01 pct).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	.....
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	do.....	.....
	Arsanilic acid 90 (0.01 pct).	1. Broiler chickens and replacement chickens where immunity to coccidiosisis not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	do.....	.....
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	do.....	.....
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosisis not desired; prevention of coccidiosis; growth promotion and feed efficiency; improved pigmentation.	do.....	.....
	Arsanilic acid 90 (0.01 pct) plus erythromycin 92.5.	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress, withdraw 5 d before slaughter; as sole source of organic arsenic.	.....
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic.	.....
	Arsanilic acid 90 (0.01 pct) plus erythromycin 185.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	.....
	Bacitracin 4 to 50.....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate.....	.....
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	do.....	.....
	Bacitracin 100 to 200	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	do.....	.....
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis;treatment of chronic respiratory disease (air-sac infection), blue comb (nonsepcific infectious enteritis).	As bacitracin zinc.....	.....
	Bacitracin 100 to 500	Turkeys; prevention of coccidiosis; treatment of infectious sinusitis, blue comb (mud fever).	do.....	.....
	Bacitracin plus penicillin 100 to 500 (of combination).	do.....	Type D article contains 50 to 75 pct of bacitracin but not more than 125 g penicillin; as procaine penicillin; as bacitracin zinc.	.....
	Chlortetracycline 100 to 200.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis), prevention of synovitis.	Not for laying chickens, as chlortetracycline hydrochloride.	.....
	Erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As erythromycin thiocyanate.....	.....
	Erythromycin 92.5....	1. Broiler chickens and replacement chickens where immunity to coccidiosisis not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.	.....
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 7 to 14 d; withdraw 24 h before slaughter.....	.....

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Erythromycin 185.....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Hygromycin B 8 to 12.	Broiler chickens and replacement chickens where immunity to coccidiosisis not desired; prevention of coccidiosis; control of infestation of large roundworms (*Heterakis gallinae*) and capillary worms (*Capillaria obsignata*).	Feed according to subtable in item (i)	
	Penicillin 2.4 to 50....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As procaine penicillin	
		2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	do	
	Penicillin plus streptomycin 90 to 180 (of combination).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	Type D article contains 16.7 pct penicillin; as procaine penicillin; as streptomycin sulfate.	
		2. Turkeys; prevention of coccidiosis; treatement of infectious sinusitis, blue comb (mud fever), hexamitiasis.	Type D article contains not less than 2.4 g of penicillin nor less than 12 g of streptomycin; as procaine penicillin; as streptomycin sulfate.	
	Roxarsone 22.7 to 45.4 (0.0025 to 0.005 pct).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
		2. Turkeys; prevention of coccidiosis; growth promotion.	do	
(v) 227 (0.0025 pct).	.....	Laying chickens; treatment of coccidiosis	For severe outbreaks of coccidiosis; administer for 2 weeks.	

§ 558.58 Amprolium and ethopabate.

(a) *Approvals.* Type A medicated feed articles; 0.15 percent amprolium, 0.004 percent ethopabate, and 100 g/ton bacitracin (as bacitracin methylene disalicylate) to No. 047019 in § 510.600(c) of this chapter, amprolium and ethopabate as provided by No. 000006, bacitracin (as bacitracin methylene disalicylate) as provided by No. 046573.

(b) *Assay limits.* (1) Amprolium: Type D medicated feed article: 80 to 120 percent of labeled amount.

(2) Ethopabate: Type D medicated feed article: 80 to 120 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing amprolium and ethopabate as the sole drugs, processed from Type C medicated feed articles containing not more than 0.05 percent amprolium and 0.016 percent ethopabate, and conforming to the requirements of paragraph (e) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act. Do not use in Type B, C, or D articles containing bentonite.

(d) *Related tolerances.* See §§ 556.50 and 556.260 of this chapter.

(e) *Conditions of use.* (1) It is used in Type D medicated feed articles for chickens as follows:

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) Amprolium 113.5 (0.0125 pct) and ethopabate 3.6 (0.0004 pct).	.....	Broiler chickens as an aid in the prevention of coccidiosis.	Not for laying hens; as sole source of amprolium	
(ii) Amprolium 113.5 (0.0125 pct) and ethopabate 3.6 (0.0004 pct).	Bambermycins 2 to 3 plus roxarsone 22.8 to 34.1 (0.0025 pct to 0.00375 pct).	Broiler chickens; as an aid in the prevention of coccidiosis, for increased rate of weight gain, improved feed efficiency, and pigmentation.	Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 000006 in sec. 510.600(c) of this chapter, roxarsone by No. 017210, bambermycins by No. 000039; withdraw 5 d before slaughter.	
	Lincomycin 2 to 4	Broiler chickens; for increase in rate of weight gain; improved feed efficiency; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; as sole source of amprolium.	
	Lincomycin 2 to 4 plus roxarsone 45.4 (0.005 pct).	Broiler chickens; for increase in rate of weight gain; improved feed efficiency and; pigmentation; as an aid in the prevention of coccidiosis.	Not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic.	
	Roxarsone 45.4 (0.005 pct).	Broiler chickens; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium; do not use as a treatment for outbreaks of coccidiosis; feed as sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; roxarsone as provided by No. 017210 in sec. 510.600(c) of this chapter; combinations as provided by No. 000006.	
(iii) Amprolium 113.5 (0.015 pct) and ethopabate 36.3 (0.004 pct).	.....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur.	Not for chickens over 16 weeks of age	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improve pigmentation.	Not for laying hens; withdraw 5 d before slaughter; as sole source of organic arsenic; as erythromycin thiocyanate.	
	Bacitracin 4 to 50.....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for	Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis; as bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by No. 012769 in sec.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		increased rate of weight gain in broiler chickens raised in floor pens.	510.600(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; combination as provided by No. 000006 in sec. 510.600(c) of this chapter.	
	Bacitracin 5 to 35 plus roxarsone 34 (0.00375 pct).	Broiler chickens; for increased rate of weight gain and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 000006 in sec. 510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 or bacitracin zinc as provided by No. 012769 in sec. 510.600(c) of this chapter; roxarsone as provided by No. 017210 in sec. 510.600(c) of this chapter; combination as provided by No. 000006 in sec. 510.600(c) of this chapter.	
	Bacitracin 20 to 35 plus roxarsone 34 (0.00375 pct).	Broiler chickens; for increased rate of weight gain, improved feed efficiency, and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur in broiler chickens raised in floor pens.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by No. 000006 in sec. 510.600(c) of this chapter; bacitracin methylene disalicylate as provided by No. 046573 in sec. 510.600(c) of this chapter; roxarsone as provided by No. 017210 in sec. 510.600(c) of this chapter; combination as provided by No. 000006 in sec. 510.600(c) of this chapter.	
	Bambermycins 1 to 3	Broiler chickens; as an aid in the prevention of coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain, and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium; amprolium and ethopabate as provided by No. 000006 in sec. 510.600(c) of this chapter, bambermycins as provided by No. 000039 in sec. 510.600(c) of this chapter.	
	Bambermycins 1 to 3 plux roxarsone 22.8 to 34.1 (0.0025 pct to 0.00375 pct).	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain; improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration; as source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 000006 in sec. 510.600(c) of this chapter, roxarsone by No. 017210, bambermycins by No. 000039. Withdraw 5 d before slaughter.	
	Erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	Not for laying hens; withdraw 24 h before slaughter; as erythromycin thiocyanate.	
(iv) Amprolium 113.5 to 227 (0.0125 to 0.025 pct) and ethopabate 3.6 (0.0004 pct).		For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	Not for laying hens	
	Arsanilic acid 90 (0.01 pct).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 92.5.	1. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic; not for laying hens.	
		2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation.	Feed for 7 to 14 d; withdraw 5 h before slaughter; as sole source of organic arsenic; not for laying hens.	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 185.	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate; not for laying hens	
	Bacitracin 100 to 200	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	do	
		2. For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	As zinc bacitracin, not for laying hens	
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005 pct).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As bacitracin methylene disalicylate; not for laying hens; as sole source of organic arsenic; withdraw 5 d before slaughter.	

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Chlortetracycline 100 to 200.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.	Not for laying hens; as chlortetracycline hydrochloride	
	Chlortetracycline 200.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease caused by strains of *Mycoplasma gallisepticum* susceptible to chlortetracycline.	In low calcium Type D article containing 0.8 pct dietary calcium and 1.5 pct sodium sulfate; feed continuously as sole ration for not more than the 1st 3 weeks of life; not for laying hens.	
	Erythromycin 92.5	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; not for laying hens.	
		2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed to 7 to 14 d; withdraw 24 h before slaughter; not for laying hens.	
	Erythromycin 185	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Penicillin 2.4 to 50	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Not for laying hens; as procaine penicillin	
	Penicillin plus streptomycin 90 to 180 (of combination).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	Type D article contains 16.7 pct penicillin; as procaine penicillin; as streptomycin sulfate; not for laying hens.	
	Roxarsone 22.7 to 45.5 (0.0025 to 0.005 pct).	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	As sole source of organic arsenic; withdraw 5 d before slaughter; not for laying hens.	
(v) Amprolium 136.2 (0.015 pct) and ethopabate 3.6 (0.0004 pct).	Bacitracin 10	Broiler chickens, as an aid in the prevention of coccidiosis; growth promotion and feed efficiency.	Feed as sole ration; use as sole source of amprolium; do not feed to laying hens as bacitracin methylene disalicylate.	047019

§ 558.60 Arsanilate sodium.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article 75 to 125 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing arsanilate sodium as the sole drug and conforming to the requirements of paragraph (e) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.60 of this chapter.

(e) *Conditions of use.* (1) It is used in this Type D medicated feed article for chickens and turkeys as follows:

(i) *Grams per ton.* 90 (0.01 percent).

(ii) *Indications for use.* For growth promotion and feed efficiency; improving pigmentation.

(iii) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) Arsanilate sodium may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Zoalene in accordance with § 558.680.

§ 558.62 Arsanilic acid.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 75 to 125 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing arsanilic acid as the sole drug and conforming to the requirements of paragraph (e) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.60 of this chapter.

(e) *Conditions of use*—(1) It is used in the Type D medicated feed article for chickens and turkeys as follows:

Arsanilic acid in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
90 (0.01 pct)		1. Chickens; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
		2. Turkeys; growth promotion and feed efficiency; improving pigmentation.	do	
	Erythromycin 4.6 to 18.5.	Chickens; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Erythromycin 92.5	1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficienty; improving pigmentation.	As erythromycin thiocyanate; feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic.	
		2. Chickens; as an aid in the prevention of infections coryza; growth promotion and feed efficienty; improving pigmentation.	As erythromycin thiocyanate; feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Erythromycin 185	Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation.	As erythromycin thiocyanate; feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	

(2) Arsanilic acid may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) bacitracin zinc in accordance with § 558.78.

(iv) Bacitracin and zoalene in accordance with § 558.680.

(v) Buquinolate in accordance with § 558.105.

(vi) Zoalene in accordance with § 558.680.

§ 558.76 Bacitracin methylene disalicylate.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 70 to 130 percent of labeled amount.

(c) *Special considerations.* (1) The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

(2) Type D medicated feed articles containing bacitracin methylene disalicylate and conforming to the requirements of paragraph (e)(1) and (e)(2) are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.70 of this chapter.

(e) *Conditions of use.* (1) It is used as bacitracin methylene disalicylate in the Type D medicated feed article as follows:

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4 to 50		Chickens, turkeys, and pheasants; growth promotion and feed efficiency.		
(ii) 5 to 20		Quail; not over 5 weeks of age; growth promotion and feed efficiency.		
(iii) 10 to 50		1. Swine; growth promotion and feed efficiency		
		2. Chickens; maintaining or increasing egg production.	Feed 50 g per ton 1st 4 to 6 weeks of egg production; 10 to 50 g per ton for remainder of egg-laying period.	
(iv) 50 to 100		1. Chickens; prevention of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).		
		2. Swine; aid in prevention of bacterial swine enteritis.		
		3. Turkeys; prevention of infectious sinusitis, blue comb (mud fever).		
(v) 100		1. Chickens; maintaining or increasing hatchability of eggs.		
		2. Chickens; during times of stress, prevention of diseases named in this section caused by organisms susceptible to bacitracin.		
		3. Chickens; prevention of early mortality of chicks due to susceptible organisms.	For chicks; in starter ration	
		4. Swine; treatment of bacterial swine enteritis		
100 of combination.	Penicillin	1. Chickens; maintaining or increasing hatchability of eggs.	Type D article combination containing 75 g of bacitracin plus 25 g of penicillin; as procaine penicillin.	
		2. Swine; treatment of bacterial swine enteritis	Type D article containing 50 to 75 pct of bacitracin; as procaine penicillin.	
(vi) 100 to 200		1. Chickens; treatment of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).		
		2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).		
100 to 200 of combination.	Penicillin	1. Chickens; treatment of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).	Type D article containing not less than 25 g of penicillin nor less than 50 g of bacitracin; as procaine penicillin.	
		2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).	do	

(2) It is used as bacitracin methylene disalicylate in Type C or D medicated feed article for cattle as follows:

(i) *Amount.* 70 milligrams per head per day.

(a) *Indications for use.* Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(b) *Limitations.* Administer continously throughout the feeding period.

(ii) *Amount.* 250 milligrams per head per day.

(a) *Indications for use.* Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(b) *Limitations.* Administer continously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.

(3) it is used as bacitracin methylene disalicylate in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium with ethopabate in accordance with § 558.58.

(iii) Arsanilic acid with zoalene in accordance with § 558.680.

(iv) Carbarsone (not U.S.P.) in accordance with § 558.120.

(v) Diethlstilbestrol in accordance with § 558.225.

(vi) Hygromycin B in accordance with § 558.274.

(vii) Monensin in accordance with § 558.355.

§ 558.78 Bacitracin, zinc.

(a) *Approvals.* (1) Type A medicated feed article of 50 grams bacitracin per pound granted to No. 046573 in § 510.600(c) of this chapter.

(2) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 70 to 130 percent of labeled amount.

(c) *Special considerations.* (1) The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

(2) Type D medicated feed articles containing bacitracin zinc and conforming to the requirements of paragraph (e) (1) and (2) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.70 of this chapter.

(e) *Conditions of use.* (1) It is used as zinc bacitracin in the Type D medicated feed article as follows:

Bacitracin, zinc in grams per ton	Combination (grams per ton)	Inidcations for use	Limitations	Sponsor
(i) 4 to 50		1. Chickens turkeys, and pheasants; growth promotion and feed efficiency.		
		2. Chickens, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency.	Growing chickens, turkeys, and pheasants	016573
(ii) 5 to 20		1. Quail; growth promotion and feed efficiency	In quail not over 5 weeks of age	
		2. Quail; for increased rate of weight gain and improved feed efficiency.	Growing quail; feed as Type D article to starting quail through 5 weeks of age.	016573
(iii) 10 to 50		1. Swine; growth promotion and feed efficiency		

Bacitracin, zinc in grams per ton	Combination (grams per ton)	Indications for use	Limitations	Sponsor
		2. Chickens; maintaining or increasing egg production.	Feed 50 g per ton 1st 4 to 6 weeks of egg production; 10 to 50 g per ton for remainder of egg-laying period.	
(iv) 50 to 100		1. Chickens; prevention of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).		
		2. Turkeys; prevention of infectious sinusitis, blue comb (mud fever).		
		3. Swine; aids in the prevention of bacterial swine enteritis.		
(v) 100		1. Chickens; maintaining or increasing hatchability of eggs.		
		2. Chickens; during times of stress, prevention of diseases named in this section caused by organisms susceptible to bacitracin.		
		3. Swine; treatment of bacterial swine enteritis		
100 of combination.	Penicillin	Swine; treatment of bacterial swine enteritis	Type D article containing 50 to 75 pct bacitracin; as procaine penicillin.	
(vi) 100 to 500		1. Chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).		
		2. Chickens; prevention of early mortality of chicks due to susceptiable organisms.	For chicks; in starter feed	
		3. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).		
100 to 500 of combination.	Penicillin	1. Chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).	Type D article containing not less than 50 pct nor more than 75 pct of bacitracin except that it contains not more than 125 g of penicillin; as procaine penicillin.	
		2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).	do	

(2) It is used in a Type D medicated feed article for growing cattle, in an amount providing not less than 35 milligrams and not more than 70 milligrams per animal per day to aid in stimulating growth and improving feed efficiency.

(3) Bacitracin zinc is used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium with ethopabate in accordance with § 558.58.

(iii) Arsanilic acid and zoalene in accordance with § 558.680.

(iv) Diethylstilbestrol in accordance with § 558.225.

(v) Hygromycin B in accordance with § 558.274.

(vi) Monensin in accordance with § 558.355.

(vii) Zoalene in accordance with § 558.680.

§ 558.95 Bambermycins.

(a) *Specifications.* Bambermycins are the dried fermentation residues produced by the fermentation of *Streptomyces bamergiensis, Streptomyces ghanaensis, Streptomyces ederensis, Streptomyces geysiriensis,* and mutants and variants of these organisms.

(b) *Approvals.* Type A medicated feed article, 2 grams of bambermycins activity per pound of Type A article, see No. 000039 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type A medicated feed article: 90 to 110 percent of labeled amount of bambermycins activity. Type D medicated feed article: 70 to 130 percent of the labeled amount of bambermycins activity.

(d) [Reserved]

(e) *Conditions of use*—(1) *Broiler chicken Type D medicated feed article.* It is used as follows:

(i) *Amount per ton.* 1 to 2 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (0.125 percent) plus ethopabate, 36.3 grams (.004 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina, E. maxima,* and *E. brunetti* is likely to occur. For increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium; amprolium and ethopabate as provided by No. 000006 in § 510.600(c) of this chapter.

(iii) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus ethopabate, 36.3 grams (.004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina, E. maxima,* and E. *brunetti* is likely to occur. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium and ethopabate as provided by No. 000006 in § 510.600(c) of this chapter, roxarsone as provided by No. 017210 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(iv) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus ethopabate, 3.63 grams (.0004 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic: amprolium and ethopabate as provided by No. 000006 in § 510.600(c) of this chapter, roxarsone as provided by No. 017210 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(v) *Amount per ton.* Bambermycins, 1 to 3 grams plus amprolium, 113.5 grams (.0125 percent) plus roxarsone, 22.8 to 34.1 grams (.0025–.00375 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; amprolium as provided by No. 000006 in § 510.600(c) of this chapter, roxarsone as provided by No. 017210 in § 510.600(c) of this chapter. Withdraw 5 days before slaughter.

(vi) *Amount per ton.* Bambermycins, 1 gram plus monensin, 90 to 110 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bambermycins provided by No. 000039 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Bambermycins, 1 gram plus monensin, 90 to 110 grams plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent).

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *e. necatrix, E tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; use as sole source of organic arsenic; withdraw 5 days before

slaughter; as monensin sodium provided by No. 000986 in § 510,600(c) of this chapter; as bambermycins provided by No. 000039 in § 510.600(c) of this chapter; as roxarsone provided by No. 017210 in § 510.600(c) of this chapter.

(viii) *Amount per ton.* Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent).

(*a*) *Indications for use.* As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; zoalene as provided by No. 025700 in § 510.600(c) of this chapter.

(ix) *Amount per ton.* Bambermycins, 1 gram plus zoalene, 113.4 grams (0.0125 percent) plus roxarsone, 22.7 grams (0.0025 percent).

(*a*) *Indications for use.* As an aid in the prevention and control of coccidiosis; for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* Do not feed to chickens over 14 weeks of age; feed continuously as sole ration; feed as sole source of organic arsenic; withdraw 5 days before slaughter; zoalene as provided by No. 025700, roxarsone as provided by No. 017210 in § 510.600(c) of this chapter.

(2) *Growing-finishing swine Type D medicated feed article.* It is used as follows:

(i) *Amount per ton.* 2 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Feed continuously as sole ration.

(iv) *Special considerations.* Type D medicated feed articles processed from Type C medicated feed articles that contain up to 40 grams of bambermycins per ton and conform to the requirements of this section are not required to comply with the provisions of section 512(m) of the act.

§ 558.105 **Buquinolate.**

(a) *Chemical name.* Ethyl 4-hydroxy - 6, 7 - diisobutoxy - 3 - quinoline- carboxylate.

(b) *Approvals.* Type A medicated feed article: 16.5 and 22 percent, see No. 000947 and § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 80 to 120 percent of the labeled amount.

(d) *Special considerations.* Maximum level permitted in Type D medicated feed article: 0.011 percent (100 grams per ton). Do not use in Type B, C, or D articles containing bentonite.

(e) *Related tolerances.* See § 556.90 of this chapter.

(f) *Conditions of use.* It is used in Type D medicated feed article as follows:

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(*b*) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus arsanilic acid, 90 grams (0.01 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iv) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus penicillin, 2.4–50 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration; as procaine penicillin.

(v) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus bacitracin, 4–50 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration; as zinc bacitracin or bacitracin methylene disalicylate.

(vi) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus penicillin + bacitracin, 3.6–50 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* growth promotion and feed efficiency.

(*b*) *Limitations.* Feed continuously as the sole ration; not less than 0.6 gram of penicillin nor less than 3 grams of bacitracin; as procaine penicillin plus bacitracin zinc or bacitracin methylene disalicylate.

(vii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus chlortetracycline, 200 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific enteritis); prevention of synovitis.

(*b*) *Limitations.* In low calcium type D article containing 0.8 percent dietary calcium and 1 percent to 1.5 percent sodium sulfate; to be fed continuously for not more than the first 21 days of life.

(viii) *Amount per ton.* Buquinolate, 75 grams (0.00825 percent) plus lincomycin, 2–4 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused *E. tenella, E. maxima, E. necatrix, E. brunetti, E. acervulina.*

(*b*) *Limitations.* For broiler and fryer chickens; feed continuously as the sole ration.

(ix) *Amount per ton.* Buquinolate, 75–100 grams (0.00825–0.011 percent) plus roxarsone, 22.7–34.0 grams (0.0025–0.00375 percent).

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti, and E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(*b*) *Limitations.* Feed continuously as sole ration; withdrawn 5 days before slaughter; as sole course of organic arsenic; roxarsone as provided by No. 017210 in § 510.600(c) of this chapter.

(x) *Amount per ton.* Buquinolate, 100 grams (0.011 per cent) plus bacitracin, 4–15 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina;* increased rate of weight gain.

(*b*) *Limitations.* Feed continuously as the sole ration; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(xi) *Amount per ton.* Buquinolate, 100 grams (0.011 percent) combined with bacitracin, 19–35 grams.

(*a*) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. Brunetti,* and *E. acervulina;* increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* For floor raised broiler or fryer chickens, feed continuously as sole ration; as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter.

(2) *Broiler, fryer, roaster or replacement chickens*—(i) *Amount per ton.* 75–100 grams (0.00825–0.011 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(iii) *Limitations.* Feed continuously as the sole ration; do not administer

over 75 grams per ton (0.00825 percent) to replacement chickens over 20 weeks of age.

(3) *Laying or breeding chickens*—(i) *Amount per ton.* 75 grams (0.00825 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix, E. brunetti,* and *E. acervulina.*

(iii) *Limitations.* Feed to caged layers for 2 weeks following caging; feed continuously to layers and breeders kept on floors while in production or until marketed.

§ 558.115 Carbadox.

(a) *Chemical name.* Methyl 3-(2-quinoxalinylmethylene) carbazate-N^1,N^4-dioxide.

(b) *Approvals.* Type A medicated feed article: 2.2 percent (10 grams per pound), see No. 000069 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 75 to 125 percent of labeled amount.

(d) *Related tolerances.* See § 556.100 of this chapter.

(e) *Special considerations.* (1) The manufacturer of Type D medicated feed articles processed from Type C medicated feed articles does not require compliance with the provisions of section 512(m) of the act when they contain:

(i) Not more than 0.055 percent (500 grams/ton) carbadox and used as provided in paragraph (f) (1) or (2) of this section.

(ii) Not more than 0.055 percent (500 grams/ton) carbadox with not more than 0.106 percent (960 grams/ton) pyrantel tartrate when produced from a fixed combination Type C medicated feed article or from individual Type C medicated feed article and used as provided in paragraph (f)(3) of this section.

(2) Do not use in Type B, C, or D articles containing bentonite.

(f) *Conditions of use.* It is used in Type D medicated feed articles for swine as follows:

(1) *Amount per ton.* 10–25 grams (0.0011–0.00275 percent).

(i) *Indications for use.* For increase in rate of weight gain and improvement of feed efficiency.

(ii) *Limitations.* Do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in Type D medicated feed articles containing less than 15 percent crude protein.

(2) *Amount per ton.* 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); increase rate of weight gain and improve feed efficiency.

(ii) *Limitations.* Do not feed to swine weighing more than 75 pounds body weight; do not feed to swine within 10 weeks of slaughter; do not use in Type D medicated feed articles containing less than 15 percent crude protein.

(3) *Amount per ton.* Carbadox 50 grams (0.0055 percent) plus pyrantel tartrate, 96 grams (0.0106 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Do not feed to swine over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in Type D medicated feed articles containing less than 15 percent crude protein.

§ 558.120 Carbarsone (not U.S.P.).

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed articles: 85 to 115 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing carbarsone as a sole drug, processed from Type C medicated feed articles containing not more than 0.225 percent carbarsone and conforming to the requirements of paragraph (e) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.60 of this chapter.

(e) *Conditions of use.* (1) It is used in the Type D medicated feed articles for turkeys as follows:

(i) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent).

(*a*) *Indications for use.* As an aid in the prevention of blackhead.

(*b*) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(ii) *Grams per ton.* 227 to 340.5 (0.025 to 0.0375 percent) carbarsone plus 10 grams per ton bacitracin from bacitracin methylene disalicylate.

(*a*) *Indications for use.* As an aid in the prevention of blackhead; for increased rate of weight gain.

(*b*) *Limitations.* Feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.

(2) Carbarsone (not U.S.P.) may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Zoalene in accordance with § 558.680.

(ii) [Reserved]

§ 558.126 Chlormadinone acetate.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed articles: 75 to 125 percent of labeled amount.

(c) [Reserved]

(d) *Related tolerances.* See § 556.130 of this chapter.

(e) *Conditions of use.* It is used as a Type D medicated feed article in or on feed for beef heifers and beef cows as follows:

(1) *Amount.* 10 milligrams per head per day.

(2) *Indications for use.* Synchronization of estrus (heat).

(3) *Limitations.* Administer in Type D articles for 18 days; do not administer within 28 days of slaughter; do not administer to cows producing milk for food.

§ 558.128 Chlortetracycline.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed articles: 70 to 130 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing chlortetracycline and conforming to the requirements of paragraph (e) (1), (2), and (3) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.150 of this chapter.

(e) *Conditions of use.* (1) It is used in Type D medicated feed articles for cockatoos, macaws, and parrots as follows:

(i) *Amount.* 10 milligrams per gram of mash.

(ii) *Indications for use.* Treatment of psittacine birds suspected or known to be infected with psittacosis.

(iii) *Limitations.* As chlortetracycline hydrochloride.

(2) It is used in the Type D medicated feed articles for laboratory mice as follows:

(i) *Amount.* Not less than 100 grams per ton of feed.

(ii) *Indications for use.* As an aid in reducing the incidence of bacterial diarrhea.

(3) It is used in Type C or D medicated feed articles as follows:

TABLE 1.—*In type D medicated feed articles*

Chlortetracycline in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 50		1. Chickens and turkeys; growth promotion and feed efficiency.	As chlortetracycline hydrochloride	
		2. Swine; growth promotion and feed efficiency	do	
(ii) 20 to 50		1. Lambs and growing sheep; growth promotion and feed efficiency.	do	

TABLE 1.—*In type D medicated feed articles*—Continued

Chlortetracycline in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		2. Mink; growth promotion and feed efficiency; as an aid in increasing pelt size.	do	
(iii) 50 to 100		1. Chickens and turkeys; during times of stress, for prevention of diseases named in this section caused by organisms susceptible to the indicated levels of the cycline salt.	do	
		2. For chickens; prevention of chronic respiratory disease (air-sac infection).	do	
		3. For turkeys; prevention of infectious sinusitis, hexamitiasis.	do	
		4. For laying chickens; maintaining or increasing egg production or hatchability of eggs.	do	
		5. For chicks; prevention of early mortality due to organisms susceptible to chlortetracycline.	do	
		6. Swine; maintenance of weight gain in the presence of atrophic rhinitis; reduction of the incidence of cervical abscesses; prevention of bacterial swine enteritis; prevention of bacterial swine enteritis during times of stress.	do	
(v) 100 to 200		1. For chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride.	
		2. For turkeys; treatment of blue comb (nonspecific infectious enteritis, mud fever), infectious sinusitis, hexamitiasis; prevention of synovitis.	As chlortetracycline hydrochloride	
		3. For chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride as follows; In low-calcium Type D article containing 0.8 pct dietary calcium, not to be fed continuously for more than 8 weeks; in low-calcium Type D article containing 0.40 pct to 0.55 pct dietary calcium, not to be fed continuously for more than 5 d; in low-calcium Type D article containing 0.8 pct dietary calcium and 1 pct to 1.5 pct sodium sulfate, to be fed continuously for not more than the 1st 3 weeks of life..	
		4. Swine; treatment of bacterial swine enteritis	As chlortetracycline hydrochloride	
(v) 200		1. For chickens; prevention and control of coccidiosis caused by *Eimeria necatrix* and *E. tenella*.	Not to be fed to laying chickens; as chlortetracycline hydrochloride in low-calcium Type D article containing 0.8 pct dietary calcium, not to be fed continuously for more than 8 weeks; in low-calcium Type D article containing 0.8 pct dietary calcium and 1.0 pct to 1.5 pct sodium sulfate, to be fed continuously for not more than the first 3 weeks of life.	
		2. For chickens; treatment of coccidiosis caused by *Eimeria necatrix* and *E. tenella*.	Not to be fed to laying chickens; as chlortetracycline hydrochloride in low-calcium Type D article containing 0.4 pct to 0.55 pct dietary calcium, not be fed continuously for more than 5 d.	
		3. For chickens; control of synovitis	Not to be fed to laying chickens; as chlortetracycline hydrochloride.	
		4. For turkeys; control of synovitis	As chlortetracycline hydrochloride	
		5. For broiler chickens; treatment of chronic respiratory disease caused by strains of *Mycoplasma gallisepticum* susceptible to chlortetracycline.	In low-calcium Type D article containing 0.8 pct dietary calcium and 1.5 pct sodium sulfate; fed continuously as Type D article for not more than the last 3 weeks of life.	
		6. Swine; as an aid in reducing spread of leptospirosis.	Sole medication; as chlortetracycline hydrochloride	
(vi) 200 to 400		For ducks; for the control and treatment of fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.	Feed in Type D article to provide from 8 to 28 mg per pound of body weight per day depending upon age and severity of disease, for not more than 21 d; as the calcium complex of chlortetracycline equivalent to chlortetracycline hydrochloride.	
(vii) 400		1. For turkey poults not over 4 weeks of age; aid in reducing mortality due to paratyphoid caused by *Salmonella typhimurium*.	In low-calcium Type D article containing 1 pct total calcium with not less than 0.45 pct calcium from calcium sulfate; as chlortetracycline hydrochloride.	
		2. Swine; as an aid in reducing shedding of leptospirae; as an aid in reducing the abortion rate of swine and the mortality rate of newborn pigs when leptospirosis is present.	To be fed for 14 d as sole medication; as chlortetracycline hydrochloride.	
(viii) 500		For chickens; aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.	Not to be fed to laying chickens; as chlortetracyeline hydrochloride; in Type D article containing 0.8 pct dietary calcium; not to be fed continuously for more than 5 d; withdraw 24 h prior to slaughter.	

TABLE 2.—*In Type C or D medicated feed articles*

Chlortetracycline	Combination in milligrams per head per day	Indications for use	Limitations	Sponsor
Milligrams per pound of body weight per day				
(i) 0.1		For calves up to 250 lb in weight; growth promotion and feed efficiency.	In milk replacers or starter Type C or D articles	
(ii) 0.5		1. For beef cattle over 1,500 lb in weight; aid in prevention of anaplasmosis.	Not to be administered within 48 h of slaughter	
		2. For calves up to 250 lb in weight; aid in the prevention of bacterial diarrhea.	In milk replacers or starter Type C or D articles	
(iii) 5.0		For beef cattle; aid in the elimination of the carrier state of anaplasmosis.	Feed for 60 days; for use in the carrier state only; not to be fed within 10 d of slaughter. Labeling shall include a statement that a positive complement-fixation test at conclusion of a 60-d feeding period does not necessarily establish that anaplasmosis carrier state is still active. To positively establish that the carrier state has been eliminated, inject blood from a suspected carrier into a splenectomized (susceptible) calf.	

TABLE 2.—*In Type C or D medicated feed articles*—Continued

Chlortetracycline	Combination in milligrams per head per day	Indications for use	Limitations	Sponsor
Milligrams per head per day				
(iv) 25 to 70		For calves; growth promotion and feed efficientcy.		
(iv) 70		1. For feedlot cattle; aid in prevention of liver abscesses.		
		2. For beef cattle up to 700 lb in weight; aid in reduction of bacterial diarrhea; aid in prevention of foot rot.		
		3. For growing cattle; growth promotion and feed efficieny.		
(vi) 85		For horses up to 1 year of age; growth promotion and feed efficiency.	Do not slaughter for food purposes	
(vii) 100		For beef cattle over 700 lb in weight; aid in reduction of bacterial diarrhea; aid in prevention of foot rot.		
(viii) 350		1. For beef cattle; aid in prevention of bacterial pneumonia and shipping fever (hemorrhagic septicemia); aid in reduction of losses due to respiratory infection (infectious rhinotracheitis, shipping fever complex).	Not to be administered within 48 h of slaughter	
		2. For beef cattle up to 700 lb in weight; aid in prevention of anaplasmosis.	do	
	Sulfamethazine 350	For beef cattle; aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.	Feed for 28 d; withdraw 7 d prior to slaughter	
(ix) 500		For beef cattle 700 to 1,000 lb in weight; aid in prevention of anaplasmosis.	Not to be administered within 48 h of salughter	
(x) 750		For beef cattle 1,000 to 1,500 lb in weight; aid in prevention of anaplasmosis.	do	

(4) Chlortetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium plus ethopabate in accordance with § 558.58.

(iii) Buquinolate in accordance with § 558.105.

(iv) Clopidol in accordance with § 558.175.

(v) Decoquinate in accordance with § 558.195.

(vi) Diethylstilbestrol in accordance with § 558.225.

(vii) Hygromycin B in accordance with § 558.274.

(viii) Robenidine hydrochloride in accordance with § 558.515.

(ix) Roxarsone in accordance with § 558.530.

(x) Zoalene in accordance with § 558.680.

§ 558.145 Chlortetracycline, procaine penicillin, and sulfamethazine.

(a) *Specifications.* (1) Chlortetracycline is the antibiotic substance produced by growth of *Streptomyces aureofaciens* or the same antibiotic substance produced by any other means and, for the purpose of this section, refers to chlortetracycline or feed grade chlortetracycline as the specified salt.

(2) Procaine penicillin is the procaine salt of the antibiotic substance produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum* or the same antibiotic substance produced by any other means and, for the purposes of this section, refers to procaine penicillin or feed grade procaine penicillin.

(3) Sulfamethazine is the chemical N'-(4,6-dimethyl-2-pyrimidinyl) sulfanilamide.

(4) The antibiotic activities authorized are expressed in this section in terms of the weight of the appropriate antibiotic standards.

(5) Type D medicated feed articles contain in each ton, 100 grams of chlortetracyline, 50 grams of penicillin as procaine penicillin, and 100 grams of sulfamethazine.

(b) *Approvals.* Type A medicated feed articles, 20 grams of chlortetracycline per pound, 4.4 percent of sulfamethazine, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound; see Nos. 000196 and 010042 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed articles: 70 to 130 percent of labeled amount of chlortetracycline and procaine penicillin and 80 to 120 percent of labeled amount of sulfamethazine.

(d) *Special considerations.* Type D medicated feed articles conforming to the requirements of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See §§ 556.150, 556.510, and 556.670 of this chapter.

(f) *Conditions of use.* (1) It is administered to swine in a Type D medicated feed article for reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery); prevention of these diseases during times of stress; maintenance of weight gains in the presence of atrophic rhinitis; growth promotion and increased feed efficiency in swine weighing up to 75 pounds.

(2) Withdraw 7 days prior to slaughter.

§ 558.1 Chlortetracycline, procaine penicillin, and sulfathiazole.

(a) *Specifications.* (1) Chlortetracycline is the antibiotic substance produced by growth of *Streptomyces aureofaciens* or the same antibiotic substance produced by any other means and, for the purpose of this section, refers to chlortetracycline or feed grade chlortetracycline as the specified salt.

(2) Procaine penicillin is the procaine salt of the antibiotic substance produced by the growth of *Penicillium notatum* or *Penicillium chrysogenum* or the same antibiotic substance produced by any other means and, for the purposes of this section, refers to procaine penicillin or feed-grade procaine penicillin.

(3) Sulfathiazole is the chemical *N'*-2-thiazolyl-sulfanilamide.

(4) The antibiotic activities authorized are expressed in this section in terms of the weight of the appropriate antibiotic standards.

(b) *Approvals.* (1) Type A medicated feed articles, 20 grams of chlortetracycline hydrochloride per pound, 20 grams of sulfathiazole per pound, and procaine penicillin equivalent in activity to 10 grams of penicillin per pound, see No. 025001 in § 510.600(c) of this chapter.

(2) Type A medicated feed article, 40 grams of chlortetracycline hydrochloride, 40 grams of sulfathiazole, and procaine penicillin equivalent to 20 grams of penicillin per pound, to No. 025001 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 70 to 130 percent of labeled amount of chlortetracycline and procaine penicillin and 80 to 120 percent of labeled amount of sulfathiazole.

(d) *Special considerations.* Type D medicated feed articles conforming to the requirements of this section are exempt from the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See §§ 556.150, 556.510, and 556.690 of this chapter.

(f) *Conditions of use.* It is used in Type D medicated feed articles for swine as follows:

(1) *Amount per ton.* Chlortetracycline, 100 grams plus penicillin, 50 grams plus sulfathiazole, 100 grams.

(2) *Indications for use.* For increased rate of weight gain and improved feed efficiency in animals up to 6 weeks postweaning. For increased rate of weight gain in animals from 6 to 16 weeks postweaning. Maintenance of weight gains in the presence of atrophic rhinitis; reduction of the incidence of cervical abscesses; treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleroesuis* and vibrionic dysentery).

(3) *Limitations.* For swine raised in confinement (dry-lot) or on limited pasture; withdraw 7 days prior to slaughter; as procaine penicillin and chlortetracycline hydrochloride, as follows:

Minimum amount of type D medicated feed article which the animal should consume

Type of feed	Approximate body weight in pounds	Minimum desired daily feed intake in pounds
Prestarter (up to 6 weeks' postweaning)	20	1
Starter (up to 6 weeks' postweaning)	50	1½
Grower (6 to 16 weeks' postweaning)	80	2
Finisher (6 to 16 weeks' postweaning)	150	3

§ 558.175 **Clopidol.**

(a) *Chemical name.* 3,5-Dichloro-2, 6-dimethyl-4-pyridinol.

(b) *Approvals. (1) Type A medicated feed article of 25-percent clopidol to No.025700 in § 510.600(c) of this chapter.*

(2)Type A medicated feed article of 0.0345 percent clopidol with or without 0.0138 percent roxarsone to No. 112286 in § 510.600(c) of this chapter.

(3) type A medicated feed article, combinations of clopidol 25 percent, roxarsone 10 percent, and bacitracin methylese disalicylate, 4, 10, 15 or 25 grams per pounds, to No. 025700 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D. medicated feed articles: 80 to 120 percent of labeling amount.

(d) *Related tolerances:* See § 566.160 of this chapter.

(e) *Conditions of use.* Is is used in Type D medicated feed articles for animals has follows:

(1) *Broilar chickens—(i) Amount per ton. Clopidol 113.5 grams (0.0125 percent).*

(a) *Indications for use.* Aid in the prevention of cocidiosis caused by *E. tevella, E. Necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) *Limitations.* Do not feed to chickens over 16 weeks of age.

(ii) *Amount per ton.* Clopidol, 113.5 grams (0.125 percent) plus roxarsone 45.4 grams (0.005 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improved pigmentation.

(b) *Limitations.* Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus roxarsone, 45.4 grams (0.005 percent) plus bacitracin, 4–25 grams.

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improved pigmentation; increased rate of weight gain.

(b) *Limitations.* Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate, provided by No. 046573 in § 510.600(c) of this chapter; or as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter.

(iv) *Amount per ton.* Clopidol, 113.5 grams (0.0125%) plus zinc bacitracin, 5 to 25 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) *Limitations.* Feed continuously as sole ration. Zinc bacitracin as provided by No. 012769 in § 510.600(c) of this chapter.

(v) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus bacitracin methylene disalicylate, 4 to 50 grams per ton.

(a) *Indications for use.* For increased rate of weight gain; to aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti.*

(b) *Limitations.* Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Clopidol, 113.5 grams (0.0125 percent) plus lincomycin, 2–4 grams.

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. axima, E. brunetti,* and *E. mivati;* increase in rate of weight gain and improved feed efficiency.

(b) *Limitations.* As lincomycin hydrchloride monohydrate; do not feed to chickens over 16 weeks of age.

(2) *Broiler chickens and replacement chickens—(i) Amount per ton.* Clopidol, 113.5 or 227 grams (0.0125 or 0.025 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) *Limitations.* Feed up to 16 weeks of age if intended for use as caged layers; feed continuously as the sole ration; withdraw 5 days before slaughter if given at the level of 0.025 percent in type D article or reduce level to 0.0125 percent 5 days before slaughter.

(ii) *Amount per ton.* 113.5 grams (0.0125 percent) clopidol with 200 grams chlortetracycline.

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti,* and infectious synovitis caused by *Mycoplasma synoviae.*

(b) *Limitations.* Feed continuously as sole ration from the time chicks are placed in floor pens, up to 21 days of age.

(3) [Reserved]

(4) *Replacement chickens—(i) Amount per ton.* Clopidol 113.5 grams (0.0125 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) *Limitations.* For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age.

(ii) *Amount per ton.* Clopidol 113.5 grams (0.0125 percent) plus roxarsone 45.4 grams (0.005 percent).

(a) *Indications for use.* Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improving pigmentation.

(b) *Limitations.* For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.

(5) *Turkeys—(i) Amount per ton.* Clopidol 113.5 or 227 grams (0.0125 or 0.025 percent).

(ii) *Indications for use.* Aid in the prevention of leucocytozoonosis caused by *Leucocytozoon smithi.*

(iii) *Limitations.* For turkeys grown for meat purposes only; to be administered continuously in Type D article at 0.0125 or 0.025 percent clopidol as the sole ration depending upon management practices, degree of exposure, and amount of Type D article eaten; withdraw medication 5 days before slaughter.

§ 558.185 **Coumaphos.**

(a) *Chemical name. O,O*-Diethyl *O*-3-chloro - 4 - methyl - 2 - oxo - 2H - 1 - benzopyran-7-yl-phosphorothioate.

(b) *Approvals.* (1) type A medicated feed articles: 1.12, 2.0, 11.2, and 50 percent, see No. 000859 in § 510.600(c) of this chapter.

(2) Type A medicated feed articles: 1.12 and 11.2 percent for use in accordance with paragraph (f)(1)(ii) of this section; see No. 017800 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount.

(d) *Special considerations.* Warning—Coumaphos is a cloinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to colinesterase-inhibiting drugs, pesticides, or chemicals. Atropine is antidotal.

(e) *Related tolerances.* See 40 CFR 180.189.

(f) *Conditions of use.* It is used in Type D medicated feed articles as follows:

(1) *Beef and dairy cattle*—(i) *Amount.* Coumaphos 0.00012 lb. (0.054 gram) per 100 lb. body weight per day.

(*a*) *Indications for use.* As an aid in the reduction of fecal breeding flies through control of fly larvae.

(*b*) *Limitations.* Feed for the duration of fly season in a Type D medicated feed article containing 0.0033 percent or in a Type C medicated feed article containing not over 0.0066 percent coumaphos; do not feed to animals less than 3 months old; not for use in pelleted Type C or D articles.

(ii) *Amount.* Coumaphos, 0.0002 lb. (0.091 gram) per 100 lb. body weight per day.

(*a*) *Indications for use.* Control of gastorintestinal roundworms (*Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Trichostrongylus spp.*).

(*b*) *Limitations.* Feed 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days in the normal grain ration to which the animals are accustomed but not in rations containing more than 0.1 percent coumaphos; do not feed to animals less than 3 months old, do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks; do not feed in conjunction with oral drenches or with Type C or D articles containing phenothiazine. Should conditions warrant, repeat treatment at 30-day intervals.

(2) *Laying chickens*—(i) *Amount.* Coumaphos 27.2 grams per ton (0.003 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common roundworm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In Type D medicated feed article; administer continuously as the Type D article for 14 days; when reinfection occurs, treatment may be repeated but not sooner than 3 weeks after the end of the previous treatment; do not feed to chickens within 10 days of vaccination or other conditions of stress; treatment of colored breeds of commercial layers should be avoided while in production since these breeds appear to be more sensitive to coumaphos than white breeds; as sole medication; medications in general should be avoided while birds are approaching peak production; such interruption of normal feeding practices may upset the flock and lower egg production; diagnosis by competent personnel is essential; flock condition and production records should be carefully evaluated prior to treatment.

(3) *Replacement pullets*—(i) *Amount.* Coumaphos 36.3 grams per ton (0.004 percent).

(ii) *Indications for use.* For control of capillary worm (*Capillaria obsignata*) and as an aid in control of common roundworm (*Ascaridia galli*) and cecal worm (*Heterakis gallinae*).

(iii) *Limitations.* In Type D medicated feed article; administer before the onset of production; diagnosis by competent personnel is essential; administer continuously as Type D article for from 10 to 14 days; do not feed to chickens under 8 weeks of age nor within 10 days of vaccination or other conditions of stress; if birds are maintained on contaminated litter or exposed to infected birds, a second 10 to 14 day treatment is recommended but not sooner than 3 weeks after the end of the previous treatment; as sole medication; if reinfection occurs after production begins, repeat treatment as recommended for laying flocks.

§ 558.195 Decoquinate.

(a) *Chemical name.* Ethyl 6-(decyloxy)-7-ethoxy-4-hydroxy-3-quinolinecarboxylate ($C_{24}H_{35}NO_5$).

(b) *Specifications.* Assay—not less than 98 percent by ultraviolet spectrophotometry; melting-point range—242°–245° C.

(c) *Approvals.* (1) Type A medicated feed article: 6 percent to No. 011801 in § 510.600(c) of this chapter.

(2) Type A medicated feed article: 0.00828 percent to No. 012286 in § 510.600(c) of this chapter.

(d) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount.

(e) *Related tolerances in edible products.* See § 556.170 of this chapter.

(f) *Special considerations.* Bentonite should not be used in decoquinate Type B, C, or D medicated feed article.

(g) *Conditions of use.* (1) It is used in Type D medicated feed articles as follows:

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27.2 (0.003 pct).....	.....	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti.*	Do not feed to laying chickens	011801, 012286
	Bacitracin 10 to 50....	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; feed as sole ration; as zinc bacitracin provided by No. 012769 in sec. 510.600(c) of this chapter.	011801
	Chlortetracycline 200.	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. mivati, E. maxima,* and *E. brunetti;* for the treatment of chronic respiratory disease (air-sac infection), prevention of synovitis.	Do not feed to laying chickens; in low calcium Type D articles containing 0.8 pct of calcium; not to be fed continuously for more than 8 week; as chlortetracycline hydrochloride provided by No. 010012 in sec. 510.600(c) of this chapter.	011801
	Roxarsone 45.4 (0.005 pct).	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* growth promotion and feed efficiency; improving pigmentation.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of organic arsenic.	011801
27.2 (0.003 pct).....	Lincomycin 2	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. mivati,* and *E. brunetti;* for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; feed as sole ration; as lincomycin hydrochloride monohydrate provided by No. 000009 in sec. 510.600(c) of this chapter.	000009, 011801

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Roxarsone 11 to 45 (0.0012–0.005 pct) plus Bacitracin 12 to 50.	Broiler chickens; as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. mivati, E. maxima,* and *E. brunetti;* for increased rate of weight gain and improved feed efficiency.	Do not feed to laying chickens; withdraw 5 d before slaughter; as sole source of organic arsenic; as zinc bacitracin provided by No. 012769 in sec. 510.600(c) of this chapter; as roxarsone provided by No. 017210 in sec. 510.600(c) of this chapter.	011801

(2) It is used in Type C or D medicated feed articles as follows:

Decoquinate	Combination in grams per ton	Indications for use	Limitations	Sponsor
22.7 mg per 100 lb of body weight per day (0.5 mg per kilogram.	.....	Cattle; as an aid in the prevention of coccidiosis in ruminating calves and cattle caused by *Eimeria bovis* and *E. zurnii.*	Feed for at least 28 d during periods of coccidiosis or when it is likely to be a hazard. Do not feed to breeding animals or cows producing milk for food. Type D medicated feed articles for cattle should be consumed within 7 d of manufacture.	011801

§ 558.205 Dichlorvos.

(a) *Chemical name.* 2,2-Dichlorovinyl dimethyl phosphate.

(b) *Approvals.* Type A medicated feed article: 9.6 percent to No. 011461 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 80 to 130 percent of labeled amount.

(d) *Special considerations.* (1) Dichlorvos is to be included in meal or mash or mixed with feed in crumble form only after the crumble Type C or D article has been manufactured. Do not mix in Type C or D medicated feed articles to be pelleted nor with pelleted feed. Do not soak the Type C or D article or administer as wet mash. Type C or D medicated feed article must be dry when administered. Do not use in animals other than swine. Do not allow fowl access to Type C or D medicated feed articles containing this preparation or to feces from treated animals.

(2) Dichlorvos is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. If human or animal poisoning should occur, immediately consult a physician or a veterinarian. Atropine is antidotal.

(3) Labeling for Type C medicated feed articles must include a statement that containers or materials used in packaging such Type C articles are not to be reused and all such packaging materials must be destroyed after the product has been used.

(4) Type C or D medicated feed articles conforming to the requirements of this section and processed from Type C articles containing not more than 0.768 percent of dichlorvos are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See § 556.180 of this chapter.

(f) *Conditions of use.* It is used in Type C or D medicated feed articles for swine as follows:

(1) *Amount per ton.* Dichlorvos, 348 grams (0.0384 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For swine up to 70 pounds body weight, feed as sole ration for 2 consecutive days. For swine from 70 pounds to market weight, feed as sole ration at the rate of 8.4 pounds of feed per head until the Type D article has been consumed. For boars, open or bred gilts, and sows, feed as sole ration at the rate of 4.2 pounds per head per day for 2 consecutive days.

(2) *Amount per ton.* Dichlorvos, 479 grams (0.0528 percent).

(i) *Indications for use.* For the removal and control of mature, immature, and/or fourth-stage larvae of the whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) of the gastrointestinal tract.

(ii) *Limitations.* For boars, open or bred gilts, and sows, feed as sole ration at the rate of 6 pounds per head for one feeding.

(3) *Amount per ton.* Dichlorvos, 334–500 grams (0.0366–0.0550 percent).

(i) *Indications for use.* An aid in improving litter production efficiency by increasing pigs born alive, birth weights, survival to market, and rate of weight gain. Treatment also removes and controls mature, immature and/or fourth stage larvae of whipworm (*Trichuris suis*), nodular worm (*Oesophagostomum sp.*), large roundworm (*Ascaris suum*), and the thick stomach worm (*Ascarops strongylina*) occurring in the gastrointestinal tract of the sow or gilt.

(ii) *Limitations.* For pregnant swine; mix into a gestation feed to provide 1,000 milligrams per head daily during last 30 days of gestation.

§ 558.225 Diethylstilbestrol.

(a) *Approvals.* (1) Dry Type A medicated feed article of 2 grams (0.44 percent) and 10 grams (2.2 percent) of diethylstilbestrol per pound, and liquid Type A medicated feed article of 20 grams (4.4 percent) and 40 grams (8.8 percent) of diethylstilbestrol per pound, for use in manufacturing Type C or D medicated feed articles within the currently approved use levels of 5 to 20 milligrams per head per day; see No. 011801 in § 510.600(c) of this chapter.

(2) Dry Type A medicated feed article of 2 grams (0.44 percent), 4 grams (0.88 percent), and 10 grams (2.2 percent) of diethylstilbestrol per pound for use in manufacturing Type C or D medicated feed articles within currently approved use levels of 5 to 20 milligrams per head per day; see No. 024264 in § 510.600(c) of this chapter.

(3) [Reserved]

(b) *Assay limits.* Type C or D medicated feed articles containing below 0.00022 percent diethylstibestrol must have 80 to 120 percent of labeled amount. Type C or D medicated feed articles containing over 0.00022 percent diethylstilbestrol must have 85 to 115 percent of labeled amount.

(c) *Special considerations.* Maximum level of diethylstilbestrol permitted in Type C medicated feed article for cattle is 0.0044 percent.

(d) *Related tolerances.* See § 556.190 of this chapter.

(e) *Conditions of use.* (1) It is used in Type C or D medicated feed article as follows:

Diethylstilbestrol in milligrams per head per day	Combination in milligrams per head per day	Indications for use	Limitations	Sponsor
(i) 2		Fattening of sheep	Sheep; withdraw 7 d before slaughter; do not feed to breeding animals.	
(ii) 5 to 20		Fattening of beef cattle	Beef cattle; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals; feed not more than 10 mg per head per day to animals under 750 lb body weight.	021264
(iii) 10		do	Beef cattle; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
	Bacitracin 70	Fattening of beef cattle; reduction in number of liver condemnations due to abscesses in feedlot beef cattle; as bacitracin methylene disalicylate.	Beef cattle; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals. Feedlot beef cattle; administer continuously throughout the feeding period; withdraw 7 d before slaughter.	
	Bacitracin 250	do	Beef cattle; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals. Feedlot beef cattle; administer continuously for 5 d, then discontinue for subsequent 25 d, repeat the pattern during the feeding period; continue diethylstilbestrol during 25 d period.	
	Bacitracin 35 to 70	Fattening of beef cattle; growth promotion and feed efficiency; as zinc bacitracin.	Beef cattle; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
	Chlortetracycline 0.5 mg per pound of body weight per day.	Fattening of beef cattle; aid in prevention of anaplasmosis.	Beef cattle over 1,500 lb in weight; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
	Chlortetracycline 70.	1. Fattening of beef cattle; aid in prevention of liver abscesses.	Beef cattle and feedlot beef cattle; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
		2. Fattening of beef cattle; aid in reduction of bacterial diarrhea; aid in the prevention of foot rot.	Beef cattle to 700 lb in weight; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
	Chlortetracycline 100.	Fattening of beef cattle; aid in reduction of bacterial diarrhea; aid in the prevention of foot rot.	Beef cattle over 700 lb in weight; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
	Chlortetracycline 350.	1. Fattening of beef cattle; aid in prevention of bacterial pneumonia and shipping fever (hemorrhagic septicemia); aid in reduction of losses due to respiratory infection (infectious rhinotracheitis, shipping fever complex).	Beef cattle; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
		2. Fattening of beef cattle; aid in prevenion of anaplasmosis.	Beef cattle up to 700 lb in weight; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
	Chlortetracycline 500.	Fattening of beef cattle; aid in prevention of anaplasmosis.	Beef cattle 700 lb to 1,000 lb in weight; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding animals.	
	Chlortetracycline 750.	do	Beef cattle 1,000 to 1,500 lb in weight; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	
	Oxytetracycline 75 to 80.	Fattening of beef cattle; reduction in incidence and severity of liver abscesses.	Beef cattle over 100 lb in weight; as monoalkyl (C_8—C_{18}) trimethyl ammonium oxytetracycline; feed in not less than 1 lb of feed; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	

§ 558.240 Dimetridazole.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 85 to 120 percent of labeled amount.

(c) [Reserved]

(d) *Related tolerances.* See § 556.210 of this chapter.

(e) *Conditions of use.* It is used in the Type D medicated feed articles for turkeys as follows:

(1) *Amount per ton.* 136 to 182 grams (0.015 to 0.02 percent).

(i) *Indications of use.* For prevention of blackhead (histomoniasis, infectious enterohepatitis), growth promotion and feed efficiency.

(ii) *Limitations.* Feed continuously; do not feed to birds producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of dimetridazole.

(2) *Amount per ton.* 544 to 725 grams (0.06 to 0.08 percent).

(i) *Indications for use.* As an aid in the control of blackhead (histomoniasis, infectious enterohepatitis).

(ii) *Limitations.* Feed for not more than 7 days; do not feed to birds producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of dimetridazole.

§ 558.248 Erythromcin thiocyanate.

(a) *Approval*—(1) Type A medicated feed article: 2.2 percent to No. 043731 in § 510.600(c) of this chapter.

(2) [Reserved]

(b) *Assay limits*—(1) Type C or D medicated feed articles containing less than 20 grams per ton, 50 to 150 percent of labeled amount.

(2) Type C or D medicated feed articles containing over 20 grams per ton, 75 to 125 percent of labeled amount.

(c) *Special considerations.* (1) The levels of antibiotic listed are expressed in terms of the weight of erythromycin master standard. One gram of erythromycin thiocyanate is equivalent to 0.925 gram of erythromycin master standard.

(2) Type D medicated feed articles for swine, processed from Type A medicated feed articles that contain not more than 10 grams of erythromycin thiocyanate (9.25 grams of erythromycin) per pound and conform to the requirements of this section are not required to comply with the provisions of section 512(m) of the act (21 U.S.C. 360b(m)).

(d) *Related tolerances.* See § 556.230 of this chapter.

(e) *Conditions of use*—(1) It is used in Type D medicated feed articles as follows:

Erythromycin thiocyanate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 18.5		Chickens; growth promotion and feed efficiency		
(ii) 9.25 to 18.5		Turkeys; growth promotion and feed efficiency	For turkeys not over 12 weeks of age	
(iii) 9.25 to 64.75		Swine; increase in weight gain, improved feed efficiency in starter pigs (9.25 to 64.75) and grower-finishing pigs (9.25).	Starter ration for animals up to 35 lb body weight	043731
(iv) 18.5		Laying chickens; aid in increasing egg production		
(v) 92.5		1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.	
		2. Chickens; as an aid in the prevention of infectious corvza.	Feed for 7 to 14 d; withdraw 24 h before slaughter	
		3. Turkeys; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 2 d before stress and 3 to 6 d after stress	
(vi) 185		1. Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
		2. Turkeys; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed 5 to 8 d; do not use in birds producing eggs for food purposes.	

(2) It is used in type C or D medicated feed articles for feedlot beef cattle at 37 milligrams per head per day as an aid in stimulating growth and improving feed efficiency.

(3) Erythromycin thiocyanate may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) Arsanilic acid in accordance with § 558.62.

(iv) Zoalene in accordance with § 558.680.

§ 558.254 Famphur.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount.

(c) *Special considerations.* Famphur is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(d) *Related tolerances.* See 40 CFR 180.233.

(e) *Conditions of use.* It is used in type D medicated feed articles for cattle as follows:

(1) *Amount.* 1.1 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs and as an aid in control of sucking lice.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 30 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

(2) *Amount.* 2.3 milligrams per pound body weight per day.

(i) *Indications for use.* For control of grubs.

(ii) *Limitations.* For beef cattle and nonlactating dairy cows; feed for 10 days; withdraw from dry dairy cows and heifers 21 days prior to freshening; withdraw 4 days prior to slaughter.

§ 558.258 Ferrous fumarate.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 80 to 125 percent of labeled amount.

(c) [Reserved]

(d) *Conditions of use.* It is used in Type D medicated feed articles as a source of iron for the prevention of iron deficiency anemia in baby pigs, in an amount not to exceed that necessary to accomplish its intended effect.

§ 558.262 Furazolidone.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 85 to 115 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing furazolidone are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.290 of this chapter.

(e) *Conditions of use.* It is used in Type D medicated feed article for swine as follows:

(1) *Amount per ton.* 150 grams (0.0165 percent).

(i) *Indications for use.* In sows, for prevention of bacterial scours in baby pigs; growth promotion while on medication.

(ii) *Limitations.* Feed 1 week before farrowing and 2 weeks after farrowing.

(2) *Amount per ton.* 100 to 200 grams (0.011 to 0.022 percent).

(i) *Indications of use.* Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication.

(ii) *Limitations.* Feed 100 grams per ton for 5 weeks; or 150 grams per ton for 3 weeks; or 200 grams per ton for 2 weeks.

(3) *Amount per ton.* 300 grams (0.033 percent).

(i) *Indications for use.* Treatment of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery; growth promotion while on medication.

(ii) *Limitations.* Feed 10 to 14 days.

§ 558.266 Griseofulvin.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount.

(c) [Reserved]

(d) *Conditions of use.* It is used in the Type D medicated feed article for chinchillas as follows:

(1) *Amount.* 160 milligrams per pound (0.0353 percent).

(2) *Indications for use.* Prevention, treatment, and control of fungal infections caused by *Trichophyton*, and as an aid in the prevention of fur chewing associated with these fungal infections.

(3) *Limitations.* Administer as sole ration.

§ 558.274 Hygromycin B.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed articles: 75 to 125 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles for chickens containing hygromycin B as sole drug, processed from Type C medicated feed articles containing not more than 32 grams per ton hygromycin B, and conforming to the requirements of paragraph (e) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.330 of this chapter.

(e) *Conditions of use.* (1) It may be used in Type D medicated feed articles as follows:

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 8 to 12		Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).		
	Bacitracin 100	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate or zinc bacitracin	
	Bacitracin plus penicillin (100 to 200 of combination).	1. Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	Type D articles containing not less than 25 pct of penicillin plus not less than 50 pct of bacitracin; as procaine penicillin plus bacitracin methylene disalicylate.	
	do	2. Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	Type D articles containing not less than 50 pct nor more than 75 pct of bacitracin, except that it contains not more than 125 g of penicillin; as procaine penicillin plus zinc bacitracin.	
		3. Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	Type D articles containing 50 pct to 75 pct bacitracin, but not more than 125 g of penicillin, as procaine penicillin.	
	Chlortetracycline 100 to 200.	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride.	
	Penicillin 100	Chickens; control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	As procaine penicillin	
	Penicillin plus streptomycin (90 to 180 of combination).	do	Type D articles containing 16.7 pct of penicillin; as procaine penicillin plus streptomycin sulfate.	
(ii) 12		Swine; control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostenum dentatum*) and whipworms (*Trichuris suis*).	Withdraw 48 h prior to slaughter	
	Chlortetracycline 100 to 200.	Swine; control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostenum dentatum*) and whipworms (*Trichuris suis*); treatment of bacterial swine enteritis.	As chlortetracycline hydrochloride; withdraw 48 h prior to slaughter.	

(2) Hygromycin B may also be used in combination with:

(i) Amprolium in accordance with § 558.55.

(ii) Zoalene in accordance with § 558.680.

§ 558.305 Ipronidazole.

(a) *Chemical name.* 2-Isopropyl-1-methyl-5-nitroimidazole.

(b) *Approvals.* Type A medicated feed article containing 12.5 percent of the drug granted; see No. 000004 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article containing 0.00625 percent ipronidazole, 75 to 125 percent of labeled amount. Type D medicated feed article containing 0.025 percent ipronidazole; 80 to 120 percent of labeled amount. Type A medicated feed article: 98 percent to 115 percent of labeled amount.

(d) *Related tolerances.* See § 556.340 of this chapter.

(e) *Special considerations.* Type D medicated feed articles processed from Type C medicated feed articles that contain up to 0.0625 percent ipronidazole and that comply with the provisions of both this paragraph and paragraph (f) of this section is not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(f) *Conditions of use.* It is used in Type D medicated feed articles for turkeys as follows:

(1) *Amount per ton.* Ipronidazole, 56.75 grams (0.00625 percent).

(i) *Indication for use.* As an aid in the prevention of blackhead (histomoniasis). For increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Withdraw 4 days before slaughter. Do not feed to turkeys producing eggs for food.

(2) *Amount per ton.* Ipronidazole, 56.75 grams (0.00625 percent) plus sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).

(i) *Indications for use.* As an aid in the prevention of blackhead (histomoniasis) and coccidiosis caused by all Eimeria species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis;* bacterial infections due to *P. multocida* (fowl cholera).

(ii) *Limitations.* Withdraw 5 days before slaughter. Do not feed to turkeys producing eggs for food.

(3) *Amount per ton.* Ipronidazole, 227 grams (0.025 percent).

(i) *Indications for use.* For the treatment of blackhead (histomoniasis) in turkeys.

(ii) *Limitations.* Withdraw 4 days before slaughter. Do not feed to turkeys producing eggs for food. Feed for 7 days at the 0.025 percent level. Follow treatment with the preventive level (0.00625 percent) of ipronidazole.

§ 558.311 Lasalocid sodium.

(a) *Specifications.* Lasalocid sodium is the crystalline substance produced by the fermentation of *Streptomyces lasaliensis.* A minimum of 90 percent lasalocid sodium activity is derived from lasalocid A sodium.

(b) *Approvals.* Type A medicated feed article: 68 grams per pound of lasalocid sodium activity to No. 000004 § 510.600 (c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 75 to 125 percent of labeled amount.

(d) *Related tolerance.* See § 556.347 of this chapter.

(e) *Conditions of use.* It is used in feed for broiler or fryer chickens as follows:

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 68 (0.0075 pct) to 113 (0.0125).	.....	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	For broiler or fryer chickens only, feed continuously as the sole ration; withdraw 3 d before slaughter.	000004
(2) 08 (0.0075 pct).....	Roxarsone 45.4 (0.005 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mataviti,* and *E. maxima* and as an aid in the reduction of oocysts and lesions due to *E. tenella.*	For broiler or fryer chickens only; feed continuously as the sole ration; as sole source of organic arsenic; withdraw 5 d before slaughter; roxarsone provided by No. 017210 in sec. 510.600(c) of this chapter.	000004
(3) 68 (0.0075 pct).....	Lincomycin 2 (0.00044 pct).	Broiler or fryer chickens; for the prevention of coccidiocis caused by *Eimeria, E. brunetti, E. tenella, E. acervulina, E. maxima, E. necatrix,* for increased rate of weight gain and improved lead efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; withdraw 5 d before slaughter finished feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate.	000000

§ 558.315 Levamisole hydrochloride (equivalent).

(a) *Chemical name.* (−)-2,3,5,6,-Tetrahydro-6-phenylimidazo [2,1-*b*] thiazole monohydrochloride.

(b) *Specifications.* Assay of not less than 98 percent of nonaqueous titration with 0.1*N* potassium isoproproxide; 1 isomer minimum 95 percent pure by optical rotation.

(c) *Approvals.* Type A medicated feed article: 227 grams per pound to No. 010042 in § 510.600(c) of this chapter.

(d) *Assay limits.* Type D medicated feed article: 85 to 125 percent of labeled amount.

(e) *Related tolerances.* See § 556.350 of this chapter.

(f) *Conditions of use.* It is used in Type C or D medicated feed articles as follows:

(1) *Cattle*—(i) *Amount per ton.* 0.36–3.6 grams (0.08–0.8 percent).

(ii) *Indications for use.* Treatment of the following gastrointestinal worms and lung worm infections; stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations.* Administer Type C article mixed thoroughly in one-half

the usual amount of morning feed; mixed Type C article should be consumed within 6 hours; when Type C article feed is consumed resume normal feeding; Type C article is to be fed at the rate of 0.36 gram of levamisole hydrochloride (equivalent) per 100 lb. of body weight; conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; consult veterinarian before using in severely debilitated animals; do not administer to dairy animals of breeding age; for use in pelleted or meal Type C medicated feed articles only; the label shall bear the caution, "Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully."

(2) *Swine*—(i) *Amount per ton.* 0.36 grams (0.08 percent).

(ii) *Indications for use.* Treatment of the following nematode infections; large round worms (*Ascaris suum*), nodular worms (*Oesophagostomum spp.*). lungworms (*Metastrongylus spp.*), intestinal threadworms (*Strongyloides ransomi*).

(iii) *Limitations.* It is recommended that regular feed be withheld overnight and worming feed administered the following morning; feed 1 lb of worming feed per 100 lb. of body weight of pigs to be treated; may be fed as Type D medicated feed article or thoroughly mixed with 1 to 2 parts of regular feed prior to feeding; when Type D article is consumed, resume normal feeding. Pigs maintained under conditions of constant worm exposure may require re-treatment within 4 to 5 weeks after the first treatment due to reinfection; do not slaughter for food within 72 hours of treatment; the label shall bear the caution, "Excessive salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication. If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after Type D article is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours."

§ 558.325 Lincomycin.

(a) *Specifications.* Meets the specifications prescribed by § 453.30(a)(1) of this chapter.

(b) *Approvals.* (1) Type A medicated feed article: 4 grams per pound to No. 000009 in § 510.600(c) of this chapter for use as provided in paragraphs (f)(1) and (f)(3) of this section.

(2) Type A medicated feed article: 20 grams per pound to No. 000009 in § 510.600(c) of this chapter for use as provided in paragraph (f)(2) of this section.

(c) *Assay limits.* Type D medicated feed articles: 80 to 130 percent of labeled amount. Type A medicated feed articles: 90 to 115 percent of labeled amount.

(d) *Related tolerances in edible products.* See § 556.360 of this chapter.

(e) *Special considerations.* (1) Type D medicated feed articles for broilers containing lincomycin as the sole drug and conforming to the requirements of paragraph (f)(1) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(2) Type D medicated feed articles containing lincomycin as the sole drug, processed from Type C medicated feed articles that contain up to 2,600 grams of lincomycin per ton, and conforming to the requirements of paragraph (f)(2) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(f) *Conditions of use.*

(1) *Broilers*—It is used in Type D medicated feed articles as follows:

(i) *Amount per ton.* 2 to 4 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* As lincomycin hydrochloride monohydrate.

(ii) *Amount per ton.* 2 grams.

(*a*) *Indications for use.* For control of necrotic enteritis caused by *Clostridium spp.* or other susceptible organisms.

(*b*) *Limitations.* As lincomycin hydrochloride monohydrate.

(2) *Swine*—It is used in Type D medicated feed articles as follows:

(i) *Amount per ton.* 40 grams.

(*a*) *Indications for use.* For control of swine dysentery.

(*b*) *Limitations.* Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred; not for use in breeding swine; withdraw 6 days before slaughter.

(ii) *Amount per ton.* 100 grams; 40 grams.

(*a*) *Indications for use.* For treatment and control of swine dysentery.

(*b*) *Limitations.* Feed 100 grams per ton for 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not for use in breeding swine; withdraw 6 days before slaughter.

(iii) *Amount per ton.* 100 grams.

(*a*) *Indications for use.* For treatment of swine dysentery.

(*b*) *Limitations.* Feed as sole ration for 3 weeks or until signs of disease disappear; not for use in breeding swine; withdraw 6 days before slaughter.

(3) Lincomycin may also be used for broilers in combination with:

(i) Amprolium, ethopabate, and roxarsone in accordance with §§ 558.58 and 558.530.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) Clopidol in accordance with § 558.175.

(iv) Buquinolate in accordance with § 553.105.

(v) Decoquinate in accordance with § 558.195.

(vi) Zoalene in accordance with § 558.680.

(vii) Monensin in accordance with § 558.355.

(viii) Robenidine hydrochloride in accordance with § 558.515.

(ix) Roxarsone and monensin sodium in accordance with §§ 558.355 and 558.530.

(x) Lasalocid sodium in accordance with § 558.311.

§ 558.342 Melengestrol acetate.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 70 to 120 percent of labeled amount.

(c) [Reserved]

(d) *Related tolerances.* See § 556.380 of this chapter.

(e) *Conditions of use.* It is used in or on feed for heifers as follows:

(1) *Amount.* 0.25 to 0.50 milligram per head per day.

(2) *Indications for use.* Use for growth stimulation, improved feed utilization, and suppression of estrus (heat).

(3) *Limitations.* Heifers being fed for slaughter; administer in Type C medicated feed articles; withdraw 48 hours prior to slaughter.

§ 558.355 Monensin.

(a) *Specifications.* Monensin is the substance produced by the fermentation of *Streptomyces cinnamonensis* or the same substance produced by an other means. It is present as monensin or the sodium salt. A minimim of 90 percent of monensin activity is derived from monensin A.

(b) *Approvals.* Type A medicated feed articles containing monensin with diluent or Type B medicated feed articles containing monensin with diluent plus vitamins, minerals, and/or other nutrient ingredients granted to firms as sponsor(s) and identified by sponsor numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section are as follows:

(1) To 000986: 44 or 45 grams per lb., paragraphs (f)(1)(i) and (f)(4) of this section.

(2) To 000986: 110 grams per lb., paragraphs (f)(1) (i), (iii), (iv), (v), (ix) and (x).

(3) To 000986: 44 grams per lb. with 18 grams per lb. of roxarsone, 110 grams per lb. with 45 grams per lb. of roxarsone, paragraph (f)(1)(ii).

(4) To 012286: 303.5 grams per ton. as monensin sodium, with .038 percent roxarsone, paragraph (f)(1)(ii).

(5) To 011904: 14.67 grams per lb., as monensin sodium, paragraph (f)(1)(i).

(6) To 011904: 11.786 grams per lb., as monensin sodium, with 1.063 percent roxarsone, 22 grams per lb., as monensin sodium, with 1.98 percent roxarsone, paragraph (f)(1)(ii).

(7) To 000986: 20, 30, 45, or 60 grams per lb., as monensin sodium, paragraph (f)(3).

(c) *Assay limits.* (1) Type D medicated feed articles for chickens; 75 to 125 percent of labeled amount of monensin activity.

(2) Type D medicated feed articles for cattle:

(i) Type D articles labeled as containing 5 to 10 grams of monensin activity per ton, 80 to 120 percent of labeled amount of monensin activity.

(ii) Type D articles labeled as containing 10 to 30 grams of monensin activity per ton, 85 to 115 percent of labeled amount of monensin activity.

(2) *Special considerations.* (1) Type D medicated feed articles for chickens containing monensin as the mycelial cake shall bear an expiration date of 90 days after its date of manufacture.

(2) Type D medicated feed articles for cattle, containing 30 grams or less monensin sodium per ton shall bear an expiration date of 30 days after its date of manufacture.

(3) Type D medicated feed articles for cattle, manufactured from Type C medicated feed articles that contain not more than 1,200 grams per ton of monensin and that comply with the provisions of paragraph (f)(3) of this section are not required to comply with the requirements of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(4) Type D medicated feed articles for cattle manufactured from Type A medicated feed articles containing 20 grams per pound of monensin and that comply with the requirements of paragraph (f)(3) of this section are not required to comply with the requirements of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See § 556.420 of this chapter.

(f) *Conditions of use. It is used as follows:*

(1) *Broiler chickens*—(i) *Amount per ton.* Monensin, 90–110 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunnetti, E. mivati, and E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 72 hours before slaughter; as monensin or monensin sodium.

(ii) *Amount per ton.* Monensin, 90–110 grams, plus roxarsone, 45.4 grams (0.005 percent).

(*a*) *Indications for use.* Growth promotion and feed efficiency, improving pigmentation; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin or monensin sodium.

(iii) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 5–10 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. Acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium.

(iv) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10 grams.

(*a*) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix. E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter; as monensin sodium.

(v) *Amount per ton.* Monensin, 90–110 grams plus bacitracin, 10–30 grams.

(*a*) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter; as monensin sodium.

(vi) *Amount per ton.* Monensin, 90 to 110 grams plus bambermycins, 1 gram. See § 558.95(e)(1)(vi).

(vii) *Amount per ton.* Monensin, 90 to 110 grams plus bambermycins, 1 gram plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent). See § 558.95(e)(1)(vii).

(viii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 200 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima; and for the control of complicated chronic respiratory disease (CRD or air sac infection) caused by Mycoplasma gallisepticum* and *Escherichia coli.*

(*b*) *Limitations.* Withdraw 72 hours before slaughter; do not feed to laying chickens; feed continuously as sole ration; as monensin sodium.

(ix) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; to be fed as a sole ration, withdraw 72 hours before slaughter; as monensin sodium.

(x) *Amount per ton.* Monensin, 90–110 grams plus lincomycin, 2 grams and roxarsone, 15–45 grams.

(*a*) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 017210 in § 510.600(c) of this chapter; as monensin sodium provided by No. 000986, § 510.600(c) of this chapter; as lincomycin provided by No. 000009, § 510.600(c) of this chapter; as a combination provided by No. 000009, § 510.600(c) of this chapter.

(xi) *Amount per ton.* Monensin, 90 to 110 grams, plus lincomycin, 2 grams and roxarsone, 15 to 30 grams.

(*a*) *Indications for use.* For increase in rate of weight gain, improved feed efficiency, improved pigmentation, and as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti E. mivati* and *E. maxima.*

(*b*) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 017210 in § 510.600(c) of this chapter; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as lincomycin provided by No. 000009 in § 510.600(c) of this chapter; as a combination provided by No. 000009 in § 510.600(c) of this chapter.

(2) [Reserved]

(3) *Cattle*—(i) *Amount per ton.* Monensin, 5–30 grams.

(ii) *Indications for use.* Improved feed efficiency.

(iii) *Limitations.* Feed only to cattle being fed in confinement for slaughter; feed continuously in a Type D medicated feed article at the rate of not less than 50 nor more than 360 milligrams per head per day, as monensin sodium; do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal).

(4) *Replacement chickens intended for use as cage layers*—(i) *Amount per ton.* Monensin, 90 to 110 grams.

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti E. mivati,* and *E. maxima.*

(iii) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 72 hours before slaughter; as monensin sodium; do not feed to chickens over 16 weeks of age.

§ 558.365 Nequinate.

(a) *Chemical name.* Methyl 7-(benzyloxy) - 6 - butyl - 1,4 dihydro - 4 - oxo- 3-quinoline carboxylate.

(b) *Approvals.* (1) Type A medicated feed article: 4 percent nequinate to No. 000046 in § 510.600(c) of this chapter.

(2) Type A medicated feed article: 4 percent nequinate to No. 017800 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount of nequinate.

(d) *Related tolerances.* See § 556.440 of this chapter.

(e) *Special considerations.* Do not use in Type B, C, or D articles containing bentonite.

(f) *Conditions of use.* It is used as follows:

(1) *Broiler or fryer chickens*—(i) *Amount per ton.* Nequinate, 18.16 grams.

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(b) *Limitations.* Feed continuously as the sole ration.

(ii) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent) plus roxarsone, 45.4 grams (0.005 percent).

(a) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; for improving pigmentation.

(b) *Limitations.* Feed continuously as sole ration throughout the starting period; withdraw 5 days before slaughter; as sole source of organic arsenic.

(iii) *Amount per ton. Nequinate, 18.16 grams (0.002 percent) plus oxytetracycline, 200 grams.*

(a) *Indications for use.* For control of complicated chronic respiratory disease (air-sac infection), infectious synovitis, and treatment of blue comb (nonspecific infectious enteritis).

(b) *Limitations.* As monoalkyl (C_8–C_{18}) trimethylammonium oxytetracycline as provided by No. 000069 in § 510.600(c) of this chapter.

(2) *Roaster chickens or replacement chickens for caged layers*—(i) *Amount per ton.* Nequinate, 18.16 grams (0.002 percent).

(ii) *Indications for use.* An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(iii) *Limitations.* Feed continuously as the sole ration; do not feed to chickens over 16 weeks of age.

§ 558.366 Nicarbazin.

(a) *Approvals.* Type A medicated feed article: 25 percent of nicarbazin granted to No. 000006 in § 510.600(c) of this chapter.

(b) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount.

(c) *Related tolerances.* See § 556.445 of this chapter.

(d) [Reserved]

(e) *Conditions of use.* It is used in chicken feed as follows:

(1) *Amount per ton.* 113.5 grams (0.0125 percent).[1]

(2) *Indications for use.* As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.[1]

(3) *Limitations.* Feed continuously as the sole ration in a complete feed from the time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard: do not use as a treatment for outbreaks of coccidiosis; do not use in flushing mashes; do not feed to laying hens; withdraw 4 days before slaughter.

§ 558.367 Niclosamide.

(a) *Approvals.* Type A medicated feed article: 66 percent to No. 000859 in § 510.600(c) of this chapter.

(b) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount.

(c) *Conditions of use.* It is used for laboratory mice as follows:

(1) *Amount per ton.* 6.6 pounds (0.033 percent).

(2) *Indications for use.* Control of the mouse tapeworm *Hymenolepis nana.*

(3) *Limitations.* Feed daily for 7 consecutive days. Do not administer other drugs during treatment. If reinfection occurs, treatment may be repeated after 30 days. Do not feed to sick or debilitated animals or animals under severe stress. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. When mixed according to directions and fed free choice, the Type D article will provide a daily dose of 500 milligrams per kilogram of body weight.

§ 558.370 Nitrofurazone.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 80 to 125 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing nitrofurazone as the sole drug are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

[1] These claims are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by § 514.111 of this chapter.

(d) *Conditions of use.* It is used in Type D medicated feed articles for mink as follows:

(1) *Amount per ton.* 100 to 200 grams (0.011 to 0.022 percent).

(i) *Indications for use.* Treatment of gray diarrhea.

(ii) *Limitations.* Feed 100 grams per ton for 3 days, then 200 grams per ton for 21 days (amount of active ingredient calculated on Type D article before water added); do not repeat treatment. Discard unused mixed Type D article every 24 hours.

(2) *Amount per ton.* 100 grams (0.011 percent).

(i) *Indications for use.* Control of gray diarrhea.

(ii) *Limitations.* Feed continuously during susceptible period, not to exceed 90 days (amount of active ingredient calculated on Type D article before water added). Discard unused mixed Type D article every 24 hours.

§ 558.376 Nitromide and sulfanitran.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: nitromide, 80 to 120 percent of labeled amount; sulfanitran, 75 to 125 percent of labeled amount.

(c) [Reserved]

(d) *Related tolerances.* See §§ 556.220 and 556.680 of this chapter.

(e) *Conditions of use.* It is used in Type D medicated feed articles for chickens as follows:

(1) *Amount.* 227 grams per ton nitromide (0.025 percent) and 272 grams per ton sulfanitran (003 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix,* and *E. acervulina.*

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; from Type A articles containing not more than 25 percent nitromide and 30 percent sulfanitran.

(2) *Amount.* 227 grams per ton nitromide (0.025 percent) and 272 grams per ton sulfanitran (0.03 percent), plus 45.4 grams per ton roxarsone (0.005 percent).

(i) *Indications for use.* Prevention of coccidiosis caused by *Eimeria Tenella, E. Necatrix,* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; from Type A articles containing not more than 25 percent nitromide, 30 percent sulfanitran, and 5 percent roxarsone; as sole source of organic arsenic

§ 558.415 Novobiocin.

(a) *Specifications.* Novobiocin is the antibiotic substance produced by growth of *Streptomyces niveus* or the same antibiotic substance produced by any other means.

(b) *Approvals.* Type A medicated feed article: 25 grams of novobiocin ac-

tivity per pound to No. 000009 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount.

(d) *Special considerations.* Type D medicated feed article conforming to the requirements of this section is not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See § 556.460 of this chapter.

(f) *Conditions of use.* It is used in Type D medicated feed articles as follows:

(1) *Chickens*—(i) *Amount.* Novobiocin, 6–7 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, Type D article which contains not less than 200 grams of novobiocin acitivity per ton; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 10–14 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, Type D article which contains not less than 350 grams of novobiocin activity per ton; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) *Turkeys*—(i) *Amount. Novobiocin, 4–5 mgs. per lb. body weight per day.*

(*a*) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptable to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, Type D article which contains not less than 200 grams of novobiocin activity per ton; not for laying turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 5–8 mgs. per lb. body weight per day.

(*a*) *Indications for use.* Aid in the control of recurring outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7–8 mgs. per pound of body weight per day.

(*b*) *Limitations.* Administer, as sole ration, Type D article which contains not less than 200 grams of novobiocin activity per ton; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(iii) *Amount.* Novobiocin, 7–8 mgs. per lb. body per day.

(*a*) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infection susceptible to novobiocin; treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.

(*b*) *Limitations.* Administer, as sole ration, Type D article which contains not less than 350 grams of novobiocin activity per ton; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(3) *Mink*—(i) *Amount.* 20 mgs. per lb. body weight per day.

(ii) *Indications for use.* For treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.

(iii) *Limitaions.* Administer, as sole ration, Type D article which contains not less than 200 grams of novobiocin activity per ton; feed for 7 days.

§ 558.430 Nystatin.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 75 to 125 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing nystatin as the sole drug are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.470 of this chapter.

(e) *Conditions of use.* It is used in Type D medicated feed articles for chickens and turkeys as follows:

(1) *Amount.* 50 grams per ton.

(i) *Indications for use.* Chickens and turkeys; aid in control of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys.

(2) *Amount.* 100 grams per ton.

(i) *Indications for use.* Chickens and turkeys; treatment of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys; to be fed for 7 to 10 days.

§ 558.435 Oleandomycin.

(a) *Specifications.* It is the antibiotic substance produced by the growth of *Streptomyces antibioticus* or the same antibiotic substance produced by any other means, and for the purpose of this section refers to oleandomycin or feed grade oleandomycin.

(b) *Approvals.* Type A medicated feed article: 5 grams of oleandomycin activity per pound to No. 000069 in § 510.600(c) of this chapter.

(c) *Assay limits.* (1) Type D medicated feed articles containing up to 11.25 grams of oleandomycin per ton: 70 to 130 percent of labeled amount of product.

(2) Type C medicated feed articles containing more than 11.25 grams of oleandomycin per ton: 75 to 125 percent of labeled amount of product.

(d) *Related tolerances.* See § 556.480 of this chapter.

(e) *Special considerations.* (1) Do not use bentonite in Type B, C, or D medicated feed articles containing oleandomycin.

(2) Type C or D medicated feed articles for swine processed from other Type C medicated feed articles that contain not more than 225 grams of oleandomycin per ton and conforming to the requirements of paragraph (f)(1)(ii) of this section are not required to comply with the provisions of section 512(m) of the act.

(f) *Conditions of use.* (1) It is used in Type C and D medicated feed articles as follows:

(i) *Chickens and turkeys*—(*a*) *Amount per ton.* Oleandomycin, 1–2 grams.

(*b*) *Indications for use.* For increased rate of weight gain and improved feed efficiency for floor raised broiler chickens and growing turkeys.

(*c*) *Limitations.* Not to be used for laying hens.

(ii) *Swine*—(*a*) *Amount per ton.* Oleandomycin, 5–11.25 grams.

(*b*) *Indications for use.* For increased rate of weight gain and improved feed efficiency for confined and pasture raised swine.

(*c*) *Limitations.* Not to be used for breeding swine.

(2) [Reserved]

§ 558.450 Oxytetracycline.

(a) *Approvals.* (1) Type A medicated feed article equivalent to 10 and 50 grams per pound of oxytetracycline hydrochloride to No. 000069 in § 510.600(c) of this chapter.

(2) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 65 to 135 percent of labeled amount.

(c) *Special considerations.* (1) Type D medicated feed articles containing oxytetracycline only and conforming to the requirements of tables 1 and 2 of paragraph (e) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(2) The amount of oxytetracycline is expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(d) *Related tolerances.* See § 556.500 of this chapter.

(e) *Conditions of use.* (1) It is used as follows:

TABLE 1.—*In Type D medicated feed articles for chickens and turkeys*

Oxytetracycline in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 50		Chickens and turkeys; during times of stress, for prevention of diseases named in this section, caused by organisms susceptible to the named levels of the oxytetracycline salt.	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline.	
(ii) 50 to 100		1. Chickens; prevention of blue comb (nonspecific infectious enteritis).	do	
		2. Chickens and turkeys; prevention of early mortality of chicks and poults due to organisms susceptible to the oxytetracycline salt.	For chicks (1st 2 weeks of life); for poults (1st 4 weeks of life); as mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline.	
		3. Turkeys; prevention of hexamitiasis	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline.	
(iii) 100 to 200		1. Chickens; prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory mortality and severity during outbreaks; prevention of fowl cholera.	do	
		2. Chickens; treatment of blue comb (nonspecific infectious enteritis); prevention of infectious synovitis; control of complicated chronic respiratory disease (air-sac infection) by lowering mortality and severity of disease during outbreaks; reduction of lesion and mortality due to organisms susceptible to oxytetracycline in the presence of complicated chronic respiratory disease (air-sac infection).	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline in low-calcium Type D article containing 0.18 pct to 0.55 pct dietary calcium; not to be fed continuously for more than 5 d; low calcium Type D article feeds may be fed for a total of 3 to 5 d periods through the 1st 10 weeks of life with an interim period of 5 d between each low-calcium feeding. Not to be fed to laying chickens.	
		3. Turkeys; control of infectious sinusitis; prevention of infections synovitis.	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline.	
		4. Turkeys; control blue comb (nonspecific infections enteritis, mud fever); treatment of hexamitiasis.	do	
(iv) 200		1. Turkeys; control of infectious synovitis	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline.	
		2. Chickens; prevention of avian infectious hepatitis; prevention and control of *E. tennella*, cause of cecal coccidiosis.	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline in low-calcium Type D article containing 0.18 pct to 0.55 pct dietary calcium; not to be fed continuously for more than 5 d; low-calcium Type D article may be fed for a total of 35-d periods through the 1st 10 weeks of life with an interim period of 5 d between each low-calcium feeding. Not to be fed to laying chickens.	
		3. Chickens; control of infectious synovitis	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline.	
		4. Chickens; control of fowl cholera during periods of outbreaks.	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline; in low-calcium Type D article containing 0.18 pct to 0.55 pct dietary calcium; for 2 weeks from outbreak of disease, 5 d of low calcium and the remaining period on normal calcium; not to be fed to laying chickens.	
	Monensin 90 to 110	Broiler chickens; for the control of complicated chronic respiratory disease (CRD or air-sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli;* and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tennella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	Withdraw 72 h before slaughter; do not feed to laying chickens: feed continuously as sole ration; as monensin sodium.	000069
	Nequinate 18.16 (p.002 pct).	Broiler or fryer chickens; as an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervalina, E. maxima, E. brunetti* and *E. mivati.* For control of complicated chronic respiratory disease (air-sac infections) infectious synovitis, and treatment of blue comb (nonspecific infections enteritis).	As mono-alkyl (C_8-C_{18}) trimethyl ammonium oxytetracycline.	
(v) 500		Broiler chickens; as an aid in the reduction of mortality due to air-sacculitis (air-sac infection) caused by *Escherichia coli* sensitive to oxytetracycline.	Feed for 5 d as sole ration; treat at first clinical signs of disease; do not feed to laying hens; withdraw 24 hr prior to slaughter.	000069

TABLE 2.—*In Type D medicated feed articles for cattle*

Oxytetracycline in milligrams per head per day	Combination in milligrams per head per day	Indications for use	Limitations	Sponsor
75 to 80		Beef cattle; reduction of the incidence and severity of liver abscesses.	For beef cattle weighing over 400 lb; as mono-alkyl (C_8-C_{18}) trimethyl-ammonium oxytetracycline.	
	Diethylstilbestrol 10.	Fattening of beef cattle; reduction of the incidence and severity of liver abscesses.	For beef cattle weighing over 400 lb; as mino-alkyl (C_8-C_{18}) trimethyl-ammonium oxytetracycline; feed in not less than 1 lb of Type D article; withdraw 7 d before slaughter; do not feed to breeding or dairy animals.	

TABLE 3.—*In Type D medicated feed articles for fish*

Oxytetracycline	Combination	Indications for use	Limitations	Sponsor
(i) 250 mg per kilogram of fish per day (11.35 g per 100 lb of fish per day).		Pacific salmon; for marking of skeletal tissue	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days in Type D article containing oxytetracycline hydrochloride or mono-alkyl (C_8—C_{18}) trimethyl-ammonium oxytetracycline; fish not to be liberated for at least 7 d following the last administration of Type D article.	
(ii) 2.5 to 3.75 g per 100 lb of fish per day.		1. Salmonids; control of ulcer disease caused by *Hemophilus piscium*, furnnculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *Aeromonas liquefaciens*, and pseudomonas disease.	Administer as mono-alkyl (C_8—C_{18}) trimethyl ammonium oxytetracycline in Type D article for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of Type D article; do not administer when water temperature is below 9° C (48.2° F).	
		2. Catfish; control of bacterial hemorrhagic septicemia caused by *Aeromonas liquefaciens* and pseudomonas disease.	Administer as mono-alkyl (C_8—C_{18}) trimethyl ammonium oxytetracycline in Type D article for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of Type D article; do not administer when water temperature is below 16.7° C (62° F).	

(2) Oxytetracycline may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Robenidine hydrochloride in accordance with § 558.515.

(ii) [Reserved]

§ 558.460 Penicillin.

(a) *Specifications.* As procaine penicillin G or feed grade procaine penicillin.

(b) [Reserved]

(c) *Assay limits.* Type D medicated feed articles: 65 to 135 percent of labeled amount.

(d) *Special considerations.* Type D medicated feed articles containing penicillin and conforming to the requirements of paragraph (f)(1) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(e) *Related tolerances.* See § 556.510 of this chapter.

(f) *Conditions of use.* (1) It is used in Type D medicated feed articles as follows:

Penicillin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 1.5 to 42.5	Streptomycin 7.5 to 48.5.	Swine; growth promotion and feed efficiency	Feed not more than 50 g of type D article containing at least 1.5 g of penicillin and at least 7.5 g of streptomycin; as streptomycin sulfate.	
(ii) 2.4 to 38.0	Streptomycin 12.0 to 47.6.	Chickens and turkeys; growth promotion and feed efficiency.	Feed not more than 50 g of type D article containing at least 2.4 g of penicillin and at least 12 g of streptomycin; as streptomycin sulfate.	
(iii) 2.4 to 50		Chickens, turkeys, and pheasants; growth promotion and feed efficiency.		
(iv) 5 to 20		Quail; growth promotion and feed efficiency	Quail, not over 5 weeks of age	
(v) 10 to 50		Swine; growth promotion and feed efficiency		
(vi) 22.5 to 50 (of the combination).	Streptomycin	Chickens; maintaining or increasing egg production.	Type D article contains 16.7 pct of penicillin; as procaine penicillin, as streptomycin sulfate.	
(vii) 45 to 90 (of the combination).	do	Swine; aid in the prevention of bacterial swine enteritis.	do	
(viii) 50 to 100		1. Chickens; prevention of chronic respiratory disease (air-sac infection), blue comb (nonspecific infections enteritis).		
		2. Turkeys; prevention of infectious sinusitis, blue comb (mud fever).		
(ix) 90 (of the combi- nation).	Streptomycin	1. Chickens; prevention of early mortality caused by organisms susceptible to penicillin and streptomycin.	For chicks; in starter ration containing 16.7 pct of penicillin; as procaine penicillin, as streptomycin sulfate.	
		2. Swine; treatment of bacterial swine enteritis	Type D article contains 16.7 pct of penicillin; as procaine penicillin; as streptomycin sulfate.	
(x) 90 to 180 (of the combination).	do	1. Chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	do	
		2. Turkeys; treatment of infections sinusitis; blue comb (mud fever), hexamitiasis.	do	
(xi) 90 to 270 (of the combination).	do	Swine; treatment of bacterial swine enteritis	Type D article contains 16.7 pct of penicillin; feed not more than 14 d; procaine penicillin; as streptomycin sulfate.	
(xii) 100		1. Chickens; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific enteritis).		
		2. Turkeys; treatment of infectious sinusitis, blue comb (mud fever).		

(2) Penicillin may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium plus ethopabate in accordance with § 558.58.

(iii) Bacitracin methylene disalicylate in accordance with § 558.76.

(iv) Bacitracin zinc in accordance with § 558.78.

(v) Buquinolate in accordance with § 558.105.

(vi) Hygromycin B in accordance with § 558.274.

(vii) [Reserved]

(viii) Reserpine in accordance with § 558.505.

(ix) Roxarsone and zoalene in accordance with § 558.680.

(x) Zoalene in accordance with § 558.680.

§ 558.464 Poloxalene.

(a) *Specifications.* Poloxalene dry Type A medicated feed article and poloxalene liquid Type A medicated feed article contain poloxalene meeting the specifications given in § 520.1840 of this chapter.

(b) *Approvals.* Dry Type A medicated feed article of 53 percent and liquid Type A medicated feed article of 99.5 percent to No. 000007 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) For prevention of legume (alfalfa, clover) and wheat pasture bloat in cattle.

(2) Poloxalene dry Type A medicated feed article and liquid Type A medicated feed article must be thoroughly

blended and evenly distributed in feed prior to use. This may be accomplished by preparing a Type B medicated feed article prior to preparing the Type D medicated feed article. Dosage is 1 gram of poloxalene per 100 pounds of body weight daily and continued during exposure to bloat producing conditions. If bloating conditions are severe, the dose is doubled. Treatment should be started 2 to 3 days before exposure to bloat-producing conditions. Repeat dosage if animals are exposed to bloat-producing conditions more than 12 hours after the last treatment. Do not exceed the higher dosage levels in any 24-hour period.

§ 558.465 Poloxalene liquid Type C medicated feed article.

(a) *Specifications.* Poloxalene liquid Type C medicated feed article contains poloxalene meeting the specifications given in § 520.1840 of this chapter.

(b) *Approvals.* Type A medicated feed article of 99.5 percent to No. 000007 in § 510.600(c) of this chapter.

(c) *Assay limits.* Poloxalene liquid Type C medicated feed article: 85 to 115 percent of labeled amount.

(d) *Conditions of use.* (1) For control of legume (alfalfa, clover) and wheat pasture bloat in cattle, use 7.5 grams of poloxalene per pound of liquid Type C medicated feed article (1.65 percent weight/weight). Each animal must consume 0.2 pound of Type C article per 100 pounds of body weight daily for adequate protection.

(2) For control of legume (alfalfa, clover) bloat in cattle grazing of prebloom legumes, use 10.00 grams of poloxalene per pound of liquid Type C article (2.2 percent weight/weight). Each animal must consume 0.15 pound of Type C article per 100 pounds of body weight daily for adequate protection. If consumption exceeds 0.2 pound of Type C article per 100 pounds of body weight daily, cattle should be changed to a Type C article containing 7.5 grams of poloxalene per pound.

(3) Poloxalene liquid Type A article must be thoroughly blended and evenly distributed into a liquid Type C article and offered to cattle in a covered liquid Type C article feeder with lick wheels. The formula for the liquid Type C article, on a weight/weight basis, is as follows: Ammonium polyphosphate 2.66 percent, phosphoric acid (75 percent) 3.37 percent, sulfuric acid 1.00 percent, water 10.00 percent, and molasses sufficient to make 100.00 percent, vitamins A and D and/or trace minerals may be added. One free-turning lick wheel per 25 head of cattle must be provided.

(4) The medicated liquid Type C article must be introduced at least 2 to 5 days before legume consumption to accustom the cattle to the medicated liquid Type C article and to lick wheel feedings. If the medicated feeding is interrupted, this 2- to 5-day introductory feeding should be repeated.

§ 558.485 Pyrantel tartrate.

(a) *Approvals.* (1) Type A medicated feed articles: 10.6 and 17.6 percent (48 and 80 grams per pound) to No. 000069 in 21 CFR 510.600(c).

(2) Type A medicated feed articles: 10.6 percent (48 grams per pound) to No. 017800 in 21 CFR 510.600(c).

(b) *Assay limits.* Type D medicated feed article: 88 to 118 percent of labeled amount.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Special considerations.* (1) Consult veterinarian before using in severely debilitated animals.

(2) The manufacture of Type D medicated feed articles processed from Type C medicated feed articles does not require compliance with the provisions of section 512(m) of the act when they contain:

(i) Not more than 0.106 percent (960 grams/ton) pyrantel tartrate and used as provided in paragraph (e) (1) or (2) of this section.

(ii) Not more than 0.106 percent (960 grams/ton) pyrantel tartrate with not more than 0.055 percent (500 grams/ton) carbadox when produced from a fixed combination Type C medicated feed article or from individual Type C articles and used as provided in paragraph (e)(4) of this section.

(3) Do not mix in Type B, C, or D medicated feed articles containing bentonite.

(4) Type D articles processed from Type C articles that contain not more than 0.881 percent of pyrantel tartrate and that comply with the provisions of paragraph (e)(3) of this section are not required to comply with the provisions of section 512(m) of the act.

(5) Complete feeds processed from feed premixes that contain not more than 17.6 percent (80 grams per pound) pyrantel tartrate and comply with the provisions of paragraph (e)(1), (2), or (3) or this section are not required to comply with the provisions of section 512(m) of the act.

(e) *Conditions of use.* It is used in Type D medicated feed articles for swine as follows:

(1) *Amount per ton.* 96 grams (0.0106 percent).

(i) *Indications for use.* Aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* Feed continuously as sole ration; withdraw 24 hours prior to slaughter.

(2) *Amount per ton.* 96 grams (0.0106 percent).

(i) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) infections.

(ii) *Limitations.* Feed for 3 days as sole ration; withdraw 24 hours prior to slaughter.

(3) *Amount per ton.* 800 grams (0.0881 percent).

(i) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(ii) *Limitations.* As a single therapeutic treatment in Type D article; feed at the rate of 1 lb. of Type D article per 40 lb. of body weight for animals up to 200 lb. and 5 lb. of Type D article per head for animals 200 lb. or over; withdraw 24 hours prior to slaughter.

(4) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and carbadox, 50 grams (0.0055 percent).

(i) *Indications for use.* For control of swine dysentery (vibrionic dysentery, bloody scours or hemorrhage ,dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections, aid in the prevention of establishment of nodular worm (*Oesophagostomium*) infections.

(ii) *Limitations.* Do not feed to swine weighing over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in Type D medicated feed articles containing less than 15 percent crude protein.

§ 558.505 Reserpine.

(a) *Chemical name.* 3,4,5-Trimethoxybenzoyl methyl reserpate.

(b) *Specifications.* For the purpose of this section, the term reserpine refers to reserpine or feed grade reserpine; assay 94–102 percent (anhydrous basis).

(c) *Approvals.* Type A medicated feed article: 0.08 percent to No. 000003 in § 510.600(c) of this chapter.

(d) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount.

(e) [Reserved]

(f) *Related tolerances.* See § 556.570 of this chapter.

(g) *Conditions of use.* It is used in Type D medicated feed articles for turkeys as follows:

(1) *Amount per ton.* Reserpine, 0.182 gram (0.00002 percent).

(i) *Indications for use.* To aid in the prevention of aortic rupture.

(ii) *Limitations.* For turkeys over 4 weeks of age.

(2)–(4) [Reserved]

(5) *Amount per ton.* Reserpine, 0.908 gram (0.0001 percent).

(i) *Indications for use.* To lessen the incidence or aortic rupture.

(ii) *Limitations.* For turkeys over 4 weeks of age; feed not to exceed 5 days.

§ 558.515 Robenidine hydrochloride.

(a) *Chemical name.* 1,3-Bis(parachloro - benzylideneamino) - guanidine hydrochloride.

(b) *Approvals.* Type A medicated feed article: 30 grams per pound has been granted to No. 010042 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 80 to 120 percent of labeled amount. Type A medicated feed article: 95 to 115 percent of labeled amount.

(d) *Special considerations.* Type D medicated feed articles containing robenidine hydrochloride must be fed within 50 days from the date of manufacture. Do not use in Type B, C, or D articles containing bentonite.

(e) *Related tolerances in edible products.* See § 556.580 of this chapter.

(f) *Conditions of use.* It is used in Type D medicated feed articles for chickens as follows:

(1) *For boiler and fryer chickens*—(i) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunette, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.*

(*b*) *Limitations.* Do not feed to layers; feed continuously as the sole ration; withdraw 5 days prior to slaughter.

(ii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus roxarsone, 22.5–45.4 grams (.005 percent).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix* and increased rate of weight gain.

(*b*) *Limitations.* Do not feed to layers; feed continuously as the sole ration; withdraw 5 days prior to slaughter; as sole source of organic arsenic. Roxarsone provided by No. 017210, § 510.600(c) of this chapter.

(iii) *amount per ton.* Robenidine hydrocholride, 30 grams (0.0033 percent) plus chlortetracycline, 100 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the control of chronic respiratory disease (CRD) caused by *M. gallisepticum* susceptible to chlortetracycline; as an aid in the control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.

(*b*) *Limitations.* For broiler or fryer chickens only; withdraw 5 days prior to slaughter; do not feed to layers, feed continuously as sole ration; as chlortetracycline hydrochloride provided by No. 010042, § 510.600(c) of this chapter.

(iv) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 200 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the treatment of infectious synovitis caused by *M. synoviae suscpetible to chlortetracycline; as an aid in the control of chronic respiratory disease (CRD) caused by M. gallisepticum* susceptible to chlortetracycline.

(*b*) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to layers; feed continuously as sole ration; as chlortetracycline hydrochloride provided by No. 010042, § 510.600(c) of this chapter.

(v) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus chlortetracycline, 500 grams.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* as an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.

(*b*) *Limitations.* Withdraw 5 days prior to slaughter; do not feed to layers; not to be fed continuously for more than 5 days; as chlortetracycline hydrochloride provided by No. 010042, § 510.600(c) of this chapter.

(vi) *Amount per ton.* Robenidine hydrochloride, 30 grams (.0033 percent) plus bacitracin, 4 to 50 grams (as zinc bacitracin).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix* and, in the presence of 4 to 30 grams per ton of bacitracin, for increased rate of weight gain; in the presence of 27 to 50 grams per ton of bacitracin, for improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days prior to slaughter; as zinc bacitracin provided by No. 012769 in § 510.600(c) of this chapter.

(vii) *Amount per ton.* Robenidine hydrochloride, 30 grams (.0033 percent) plus bacitracin, 4 to 50 grams (as bactracin methylene disalicylate).

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix,* and: in the presence of 4 to 30 grams per ton of bacitracin, for increased rate of weight gain; in the presence of 27 to 50 grams per ton of bacitracin, for improved feed efficiency.

(*b*) *Limitations.* Feed continuously as sole ration; do not feed to laying chickens; withdraw 5 days prior to slaughter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.

(viii) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus lincomycin, 2 grams.

(*a*) *Indications for use.* For increase in rate of weight gain and improved feed efficiency and as an aid in prevention of coccidiosis caused by *E. mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix.*

(*b*) *Limitations.* Do not feed to laying hens; feed continuously as the sole ration; withdraw 5 days before slaughter; lincomycin as provided by No. 000009, § 510.600(c) of this chapter; approval for this combination granted to No. 000009, § 510.600(c) of this chapter.

(2) *For broiler chickens*—(i) *Amount per ton.* Robenidine hydrochloride, 30 grams (0.0033 percent) plus oxytetracycline, 200 grams.

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by *eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix;* for the control of complicated chronic respiratory disease (CRD or airsac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli.*

(iii) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; do not use in Type B, C, or D articles containing bentonite; Type C or D articles must be used within 50 days of date of manufacture; oxytetracycline as provided by No. 000069 of this chapter.

§ 558.525 Ronnel.

(a) *Chemical name. O,O*-Dimethyl *O*-(2,4,5-trichlorophenyl) phosphorothioate.

(b) *Approvals.* (1) Type A medicated feed article: 18 and 40 percent to No. 025700 in § 510.600(c) of this chapter.

(2) Type C medicated feed article: 5.5 percent in mineral mix to No. 021930 in § 510.600(c) of this chapter.

(c) *Assay limits.* Type C medicated feed article: 80 to 120 percent of labeled amount.

(d) *Special considerations.* (1) Maximum level permitted in a Type C medicated feed article is 6 percent.

(2) The label shall bear adequate directions and warnings for use, which shall also include:

(i) Type C medicated feed articles containing ronnel shall be thoroughly mixed with ground grain for top dressing or with complete ration.

(ii) A statement that ronnel-Type C articles are to be used as sole source of ronnel.

(iii) "Warning-Ronnel is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after exposure to cholinesterase inhibiting drugs, pesticides, or chemicals."

(e) *Related tolerances.* See 40 CFR 180.177.

(f) *Conditions of use.* It is used in Type C medicated feed articles for beef cattle and nonlactating dairy animals as follows:

(1) *Amount.* 0.00078 lb. (0.35 gram) per 100 lb. body weight per day for 14 days.

(i) *Indications for use.* Control of grubs.

(ii) *Limitations.* Feed 0.00078 lb. (0.35 gram) per 100 lb. of animal weight per day for 14 days in a Type C article containing not over 0.26 percent ronnel; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during feeding of a Type C article, or if Type C article has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(2) *Amount.* 0.0018 lb. (0.82 gram) per 100 lb. body weight per day for 7 days.

(i) *Indications for use.* Control of grubs; aid in the reduction of cattle lice, when the drug is used for cattle grub control.

(ii) *Limitations.* Feed 0.0018 lb. (0.82 gram) per 100 lb. animal weight per day for 7 days in a Type C article containing not over 6 percent ronnel; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during feeding of a Type C article, or if Type C article has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(3) *Amount.* 0.01375 lb. (6.24 gram) per 100 lb. body weight per month for not less than 75 days.

(i) *Indications for use.* Control of grubs and hornflies.

(ii) *Limitations.* Feed 0.25 lb. of a mineral Type C article in granular form containing 5.5 percent ronnel per 100 lb. of animal weight per month for not less than 75 days; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during feeding of a Type C article, or if Type C article has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(4) *Amount.* 0.0009 lb. (0.41 gram) per 100 lb. body weight per day for 14 days.

(i) *Indications for use.* Control of grubs.

(ii) *Limitations.* Feed 0.0009 lb. (0.41 gram) per 100 lb. of animal weight per day for 14 days in a Type C article containing 0.3 percent ronnel; withdraw from dairy animals 10 days before calving, if dairy cows or heifers freshen during feeding of a Type C article, or if Type C article has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment; withdraw 10 days prior to slaughter.

(5) *Amount.* 0.012 lb. (5.5 gram) per 100 lb. body weight per month for not less than 75 days.

(i) *Indications for use.* Control of grubs and hornflies.

(ii)*Limitations.* Feed 0.2 lb. of mineral Type C article containing 6 percent ronnel per 100 lb. of animal weight per month for not less than 75 days; withdraw from dairy animals 10 days before calving; if dairy cows or heifers freshen during feeding of a Type C article, or if Type C article has not been withdrawn the required 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment.

§ 558.526 Ronnel liquid Type C medicated feed article.

(a) *Approvals.* To No. 025700 in § 510.600(c) of this chapter, use of a 20 percent liquid Type A medicated feed article for the manufacture of a 0.72 percent ronnel liquid Type C medicated feed article.

(b) *Assay limits.* Type C medicated feed article: 80 to 120 percent of labeled amount.

(c) *Related tolerances.* See 40 CFR 180.177.

(d) *Conditions of use.* (1) It is used as a 0.72 percent liquid Type C medicated feed article for beef cattle and nonlactating dairy animals for control of grubs.

(2) Both the 7 and 14-day feeding programs require 1.75 pounds of 0.72 percent Ronnel liquid Type C medicated feed article for each 100 pounds of body weight.

(i) Feed for 7 days, 0.25 pound of 0.72 percent liquid Type C medicated feed article added to feed per 100 pounds of body weight per day.

(ii) Feed for 14 days, 0.25 pound of 0.72 percent liquid Type C medicated feed article added to feed per 200 pounds of body weight per day.

(3) Must be evenly top-dressed over the grain portion of the ration or over the mixed total ration.

(4) Treat cattle as soon as possible after heel fly activity ceases, and before grubs reach the backs of the animals. Ronnel is not fully effective during the latter stages of grub development, when grubs have reached the backs of animals.

(5) Treat southern area cattle July through September (7 or 14-day treatment). Treat northern area cattle August through October (7-day treatment) or August through December (14-day treatment).

(6) Dairy animals should be treated early in their dry period but only if the dry period occurs between the end of the adult heel fly season and before grubs reach the back of the animal.

(7) Withdraw from dairy animals 10 days before calving. If animals freshen during feeding of a Type C article, or if Type C article has not been withdrawn 10 days prior to freshening, milk must not be used for food for 10 days after the last treatment.

(8) Withdraw 10 days prior to slaughter.

(9) Warning—Ronnel is a cholinesterase inhibitor. Do not use simultaneously or within a few days before or after treatment with or exposure to any cholinesterase inhibiting drugs, pesticides, or chemicals.

(10) Use as sole source of ronnel.

(11) Do not feed animals that are sick, under stress (shipping, dehorning, castration), or that have been weaned within the preceding 3 weeks.

(12) Wash hands with soap and water after handling. This material contains a cholinesterase inhibitor. Treat symptomatically. Atropine is an antidote.

(13) This drug is toxic to fish. Keep out of lakes, streams, and ponds. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not reuse empty container; destroy it by burning or burying in noncroplands away from water supplies.

§ 558.530 Roxarsone.

(a) *Approvals.* Type A medicated feed articles; 10, 20, and 50 percent to No. 011801 in § 510.600(c) of this chapter.

(b) *Assay limits.*Type D medicated feed articles: 85 to 120 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles containing roxarsone only and conforming to the requirements of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.60 of this chapter.

(e) *Conditions of use.* It is used in Type D medicated feed articles for chickens and turkeys as follows:

(1) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent).

(2) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(3) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.

(4) *Permitted combinations.* It may be used in accordance with the provisions of this section in the combinations provided, as follows:

(i) Aklomide in accordance with § 558.35.

(ii) Amprolium in accordance with § 558.55.

(iii) Amprolium and ethopabate in accordance with § 558.58.

(iv) Bacitracin methylene desalicylate in accordance with § 558.76.

(v) Bacitracin zinc in accordance with § 558.78.

(vi) Buquinolate in accordance with § 558.105.

(vii) Chlortetracycline in accordance with § 558.128.

(viii) Clopidol in accordance with § 558.175.
(ix) Decoquinate in accordance with § 558.195.
(x) Monensin in accordance with § 558.355.
(xi) Nequinate in accordance with § 558.365.
(xii) Nitromide and sulfanitran in accordance with § 558.376.
(xiii) Robenidine hydrochloride in accordance with § 558.515.
(xiv) Sulfadimethoxine, ormetoprim in accordance with § 558.575.
(xv) Zoalene in accordance with § 558.680.
(xvi) Penicillin and zoalene in accordance with§ 558.680.
(xvii) Bambermycins alone and in combination in accordance with § 558.95.

§ 558.565 Styrylpyridinium chloride, diethylcarbamazine (as base).

(a) *Chemical name.* (1) Styrylpyridinium chloride: 2-(*p*-Chlorostyryl)-1-methylpyridinium chloride.
(2) Diethylcarbamazine: *N,N*-Diethyl - 4 - methyl - 1 - piperazine - carboxamide.
(b) *Approvals.* Type D medicated feed articles: 0.035 percent styrylpyridinium chloride, and 0.021 percent diethylcarbamazine (as base) to No. 010042 in § 510.600(c) of this chapter.
(c) *Conditions of use.* (1) it is used for the control of hookworms (*Ancylostoma caninum*) and roundworms (*Toxocara canis*) and for the prevention of heartworm disease (*Dirofilaria immitis*) in dogs.
(2) Type D medicated feed articles containing 0.035 percent styrylpyridinium chloride and 0.021 percent diethylcarbamazine (as the base) is administered to dogs as follows: Maximum stressed dogs are fed an amount of the Type D article in ounces equal to the dogs body weight in pounds divided by 4. Medium stressed dogs are fed an amount of the Type D article in ounces equal to the dogs body weight in pounds divided by 4.5. Low stressed dogs are fed an amount of the Type D article in ounces equal to the dogs body weight in pounds divided by 5. Underweight dogs are fed 10 percent more than the amounts specified in this paragraph. Overweight dogs are fed 10 percent less than the amounts specified in this paragraph, with adjustments made every 7 days until the desired body weight is obtained.
(3) Dogs with established heartworm infections should not be treated with the drug until they have been converted to a negative status. For the prevention of heartworm infestation, the drug should be administered before the mosquito season and as soon as young puppies are born. The drug should be administered continuously during periods of exposure to hookworm, roundworm, and heartworm infestations to control recurring burdens of hookworms and roundworms and prevent the maturation of immature heartworms (third stage infective larvae) into adults.
(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 558.575 Sulfadimethoxine, ormetoprim.

(a) *Chemical names.* (1) Sulfadimethoxine: *N'* (2,6-Dimethoxy-4-pyrimidinyl)-sulfanilamide.
(2) Ormetoprim: 2,4-Diamino-5(6-methylveratryl) pyrimidine.
(b) *Approvals.* Type A medicated feed articles: 25 percent of sulfadimethoxine and 15 percent of ormetoprim to No. 000004 in § 510.600(c) of this chapter.
(c) *Assay limits.* (1) Type D medicated feed articles containing 0.01 percent of combined drug: 75 to no more than 125 percent of ormetoprim and sulfadimethoxine.
(2) Type D medicated feed articles containing 0.02 percent of combined drug: 85 to 115 percent of ormetoprim and sulfadimethoxine.
(d) *Related tolerances.* See §§ 556.490 and 556.640 of this chapter.
(e) *Conditions of use.* It is used in Type D medicated feed articles for animals as follows:
(1) *Broiler chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).
(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).
(*b*) *Limitations.* Feed as sold ration; withdraw 5 days before slaughter.
(ii) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent) plus roxarsone, 22.7 grams (0.0025 percent).
(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli,* (colibacillosis); and *P. multocida* (fowl cholera); growth promotion and feed efficiency; improving pigmentation.
(*b*) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic.
(2) *Replacement chickens*—(i) *Amount per ton.* Sulfadimethoxine, 113.5 grams (0.0125 percent) plus ormetoprim, 68.1 grams (0.0075 percent).
(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to chickens, namely *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (colibacillosis) and *P. multocida* (fowl cholera).
(iii) *Limitations.* Feed as a sole ration; do not feed to chickens over 16 weeks (112 days) of age; withdraw 5 days before slaughter.
(3) *Turkeys.*—(i) *Amount per ton.* Sulfadimethoxine, 56.75 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent).
(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis* and bacterial infection due to *P. multocida* (fowl cholera).
(*b*) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 5 days before slaughter.
(ii) *Amount per ton.* Sulfadimethoxine, 56.5 grams (0.00625 percent) plus ormetoprim, 34.05 grams (0.00375 percent) plus ipronidazole, 56.75 grams (0.00625 percent).
(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by all *Eimeria* species known to be pathogenic to turkeys, namely, *E. adenoeides, E. gallopavonis,* and *E. meleagrimitis;* bacterial infections due to *P. multocida* (fowl cholera); and blackhead (histomoniasis).
(*b*) *Limitations.* Do not feed to turkeys producing eggs for food; withdraw 5 days before slaughter.

§ 558.579 Sulfaethoxypyridazine.

(a) [Reserved]
(b) *Assay limits.* Type D medicated feed article: 85 to 115 percent of labeled amount.
(c) [Reserved]
(d) *Related tolerances.* See § 556.650 of this chapter.
(e) *Conditions of use.* It is used in Type C or D medicated feed articles as follows:
(1) *Swine.*—(i) *Amount.* 25 milligrams per pound body weight per day.
(ii) *Indications for use.* For treatment of bacterial scours, pneumonia, enteritis, bronchitis, septicemia accompanying *Salmonella choleraesuis* infection.
(iii) *Limitations.* Administer 1,000 grams per ton (0.11 percent) in Type D article for not less than 4 days nor more than 10 days; do not treat within 10 days of slaughter; as sole source of sulfonamide; for use by or on the order of a licensed veterinarian.
(2) *Cattle.*—(i) *Amount.* 25 milligrams per pound body weight per day.
(ii) *Indications for use.* For treatment of respiratory infections (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(iii) *Limitations.* Administer Type C article as a top dressing or in mixed feed for 4 days; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food; for use by or on the order of a licensed veterinarian.

§ 558.582 Sulfamerazine.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 85 to 115 percent of labeled amount.

(c) [Reserved]

(d) *Related tolerances.* See § 556.660 of this chapter.

(e) *Conditions of use.* It is used in Type D medicated feed article for rainbow trout, brook trout, and brown trout as follows:

(1) *Amount.* 10 grams of sulfamerazine per 100 pounds of fish per day.

(2) *Indications for use.* Control of furunculosis.

(3) *Limitations.* Treat for not more than 14 days; do not treat within 3 weeks of marketing or stocking in stream open to fishing.

§ 558.615 Thiabendazole.

(a) *Chemical name.* 2-(4'-Thiazolyl)-benzimidazole.

(b) *Specifications.* Conforms to N.F. XII specifications.

(c) *Approvals.* In dry Type A medicated feed articles: 22, 44.1, 66.1 percent. The 66.1 percent level is solely for the manufacture of cane molasses liquid Type C medicated feed article which is mixed in dry feeds. See No. 000006 in § 510.600(c) of this chapter.

(d) *Assay limits.* Type D medicated feed articles containing less than 7 percent thiabendazole: 85–115 percent of labeled amount. Type D medicated feed articles containing 7 percent or more of thiabendazole: 90–110 percent of labeled amount.

(e) *Special consideratons.* Maximum level permitted in a Type C medicated feed article: 9.9 percent. Not to be used in Type B, C, or D articles containing bentonite.

(f) *Related tolerances.* See § 556.730 of this chapter.

(g) *Conditions of use.* It is used in Type C and D medicated feed article as follows:

(1) *Cattle.*—(i) *Amount.* 3 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Namatodirus spp., Oesophagostomum radiatum*).

(*b*) *Limitations.* Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(ii) *Amount.* 5 grams per 100 lb. body weight.

(*a*) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp.*

(*b*) *Limitations.* 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days; may repeat once in 2 to 3 weeks; do not treat animals within 3 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(2) *Goats.*—(i) *Amount.* 3 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).

(iii) *Limitations.* 3 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(3) *Sheep and goats.*—(i) *Amount.* 2 grams per 100 lb. body weight.

(ii) *Indications for use.* Control of infections of gastrointestinal roundworms *Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after Type C or D article is consumed (good activity against ova and larvae of *T. colubriformis* and *axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.*; less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).

(iii) *Limitations.* Use 2 grams per 100 lb. body weight at a single dose; do not treat animals within 30 days of slaughter; milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.

(4) *For swine.*—(i) *Amount.* 45.4–908 grams per ton (0.005–0.1 percent).

(ii) *Indications for use.* Aid in the prevention of infections of large roundworms (*genus ascaris*).

(iii) *Limitations.* Administer continuously Type D article containing 0.05–0.1 percent thiabendazole per ton for 2 weeks followed by Type D article containing 0.005–0.02 percent thiabendazole per ton for 8–14 weeks; do not treat animals within 30 days of slaughter.

§ 558.625 Tylosin.

(a) *Specifications.* Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means.

(b) *Approvals.* Type A medicated feed articles containing drug substance with diluent or Type B medicated feed articles containing drug substance with diluent plus vitamins, minerals, and/or other nutrient ingredients granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section:

(1) To 000986: 10, 40 and 100 grams per pound, paragraphs (f)(1)(ii) through (f)(1)(vi) of this section; 40 grams per pound, paragraph (f)(1)(i) of this section.

(2) To 017255: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(3) To 043733: 4 and 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(4) To 011490: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(5) To 017300: 0.4, 0.8, and 1 gram per pound, paragraph (f)(1)(vi)(*a*) of this section; 10 grams per pound, paragraph (f)(1)(i) and (vi)(*a*) of this section; 40 grams per pound, paragraph (f)(1)(i) and (vi) (*a*) (*b*) (*c*), and (*d*) of this section.

(6) To 018356: 0.66, 1.33, 6.66 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(7) To 017162: 0.4 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.

(8) To 035369: 4 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(9) To 043727: 4 and 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(10) To 012286: 0.4, 0.8, and 1.6 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(11) To 017274: 4, 8, or 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(12) To 021930: 2 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(13) To 035393: 0.4 and 2 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(14) To 016968: 4 and 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(15) To 026186: 4, 10, and 20 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(16) To 024817: 5 and 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(17) To 021780: 0.8 and 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(18) To 017434: 0.4 and 4 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(19) To 033999: 0.8 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(20) To 033071: 0.4 and 0.8 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(21) To 043426: 2.0 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(22) To 026282: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(23) To 030804: 0.8 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(24) To 025796: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(25) To 043743: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(26) To 034418: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(27) To 020275: 8 and 40 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(28) To 034139: 4 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(29) To 043744: 0.4 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(30) [Reserved]
(31) To 029341: 5 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(32) To 018597: 0.4 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(33) To 012323: 0.8 and 2 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(34) To 028260: 0.8 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(35) To 039741: 2 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(36) To 013975: 0.8 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(37) To 044142: 0.5 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(38) To 011749: 1 or 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(39) To 012518: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(40) To 035955: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(41) To 025066: 0.8 gram per pound; paragraph (f)(1)(vi)(*a*) of this section.
(42) To 010439: 0.4, 0.5, and 2 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(43) [Reserved]
(44) To 017180: 4 and 10 grams per pound: paragraph (f)(1)(vi)(*a*) of this section.
(45) To 017139: 4 and 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(46) [Reserved]
(47) To 024761: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(48) To 017790: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(49) To 021533: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(50) To 018083: 4 and 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(51) To 017519: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.
(52) To 021810: 10 grams per pound; paragraph (f)(1)(vi)(*a*) of this section.

(c) *Assay limits.* Type D medicated feed articles: 75 percent of labeled amount.

(d) *Special considerations.* The manufacture of Type D medicated feed articles containing tylosin phosphate does not require compliance with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act if:

(1) Processed from Type C articles for:

(i) Chickens at not more than 200 grams per ton.

(ii) Swine at not more than 500 grams per ton.

(iii) Cattle at not more than 360 grams per ton and complying with paragraph (f)(1)(i) of this section.

(2) Processed from Type A articles which contain not more than 10 grams of tylosin per pound and conforming to the provisions of paragraph (f)(1)(vi)(*a*) of this section.

(e) *Related tolerances.* See § 556.740 of this chapter.

(f) *Conditions of use.* (1) It is used in Type C and D medicated feed articles as follows:

(i) *For beef cattle—(a) Amount per ton.* 8–10 grams.

(*b*) *Indications for use.* For reduction of incidence of liver abscesses caused by *Sphaerophorus necrophorus* and *Corynebacterium pyogenes.*

(*c*) *Limitations.* As tylosin phosphate; each animal must receive not more than 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.

(ii) *Broiler chickens.—(a) Amounts per ton.* Tylosin, 800–1000 grams.

(*b*) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(*c*) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in Type D article to chickens 0 to 5 days of age, follow with second administration in Type D article for 24 to 48 hours at 3 to 5 weeks of age.

(iii) *Chickens—(a) Amounts per ton.* Tylosin, 4–50 grams.

(*1*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*2*) *Limitations.* As tylosin phosphate.

(b) [Reserved]

(iv) *Laying chickens—(a) Amount per ton.* Tylosin, 20–50 grams.

(*b*) *Indications for use.* For improved feed efficiency.

(*c*) *Limitations.* As tylosin phosphate.

(v) *Replacement chickens—(a) Amount per ton.* Tylosin, 1,000 grams.

(*b*) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(*c*) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in Type D article to chickens 0 to 5 days of age, follow with second administration in Type D article for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine—(a) Amount per ton.* Tylosin, 10–100 grams.

(*1*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*2*) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton;* 20–100, prestarter or starter; 20–40, grower; 10–20, finisher.

(*b*) *Amount per ton.* Tylosin, 40–100 grams.

(*1*) *Indications for use.* Prevention of swine dysentery (vibrionic).

(*2*) *Limitations.* Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.

(*c*) *Amount per ton.* Tylosin, 40–100 grams.

(*1*) *Indications for use.* Treatment and control of swine dysentery (vibrionic).

(*2*) *Limitations.* Administer in Type D article as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 gram per gallon in drinking water for 3–10 days, 40–100 grams per ton in Type D article for 2–6 weeks.

(*d*) *Amount per ton.* Tylosin, 100 grams.

(*1*) *Indications for use.* Maintaining weight gains and feel efficiency in presence of atrophic rhinits.

(*2*) *Limitations.* As tylosin phosphate

(2) [Reserved]

§ 558.630 Tylosin and sulfamethazine.

(a) *Specifications.* (1) Tylosin is the antibiotic substance produced by growth of *Streptomyces fradiae* or the same antibiotic substance produced by any other means.

(2) Sulfamethazine is the chemical N'-(4, 6-dimethyl-2-pyrimidiny) sulfanilamide.

(b) *Approvals.* Type A medicated feed articles containing drug substances with diluent, on Type B medicated feed article containing drug substances with diluent plus vitamins, minerals, and/or other nutrient substances, the drug substances being a combination of equal amounts of tylosin and sulfamethazine, granted to firms as sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section:

(1) To 000986: 40 grams per pound each, paragraph (f)(2)(i) of this section.

(2) To 000986, 012190: 10 grams per pound each paragraph (f)(2)(i) of this section.

(3) To 011490, 016968, 017255, 025796, 026186, 034500, 035955, 043743: 10 grams per pound each, paragraph (f)(2)(ii) of this section.

(4) To 021780: 2 grams per pound each, paragraph (f)(2)(ii) of this section.

(5) To 017800: 40 grams per pound each paragraph (f)(2)(ii) of this section.

(6) To 017139: 4, 10, or 20 grams per pound each, paragraph (f)(2)(ii) of this section.

(c) *Assay limits.* Type D medicated feed articles: 75 to 125 percent of tylosin and 80 to 120 percent of sulfamethazine.

(d) [Reserved].

(e) *Related tolerances.* See §§ 556.670 and 556.740 of this chapter.

(f) *Conditions of use.* It is used in Type D medicated feed articles for swine as follows:

(1) *Amount per ton.* Tylosin, 100 grams plus sulfamethazine, 100 grams.

(2) *Indications for use.* (i) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella, bronchiseptica* rhinitis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial phathogens (*P. mutocida* and/or *C. pyogens*); for reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci. Only the sulfamethazine portion of this combination is active in controlling jowl abscesses.

(ii) Maintaining weight gains and feed efficiency in the presence of atrophic rhinitis; lowering the incidence and severity of *Bordetella bronchiseptica* rhintis; prevention of swine dysentery (vibrionic); control of swine pneumonias caused by bacterial pathogens (*Pasteurella multocida* and/or *Corynebacterium pyogens*).

(3) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter.

§ 558.635 Virginiamycin.

(a) *Specifications.* Virginiamycin is the antibiotic substance produced by the growth of *Streptomyces virginiae* or the same antibiotic substance produced by any other means.

(b) Type A medicated feed articles: 2.2 percent virginiamycin activity (10 grams per pound), 11 percent virginiamycin activity (50 grams per pound), and 50 percent virginiamycin activity (227 grams per pound) to No. 000007 in § 510.600 (c) of this chapter.

(c) *Assay limits.* Type D medicated feed article: 70 to 130 percent of the labeled amount of the drug.

(d) *Related tolerances.* See § 556.750 of this chapter.

(e) *Special considerations.* (1) Not for use in breeding swine over 120 pounds.

(2) Dilute Type A article with at least 10 pounds of a feed ingredient prior to final mixing in 1 ton of Type D article.

(3) Type D medicated feed articles for swine, processed from Type C articles that contain up to 2,000 grams of virginiamycin per ton and conform to the requirements of paragraph (f) of this section are not required to comply with the provisions of section 512(m) of the act.

(f) *Conditions of use.* It is used in Type D medicated feed articles for swine as follows:

(1) *Amount per tone.* 100 grams (for 2 weeks).

(i) *Indications for use.* Treatment of swine dysentery in nonbreeding swine.

(ii) *Animal weight.* Over 120 pounds.

(2) *Amount per ton.* 100 grams for 2 weeks, 50 grams thereafter.

(i) *Indications for use.* Treatment and control of swine dysentery.

(ii) *Animal weight.* Up to 120 pounds.

(3) *Amount per ton.* 25 grams.

(i) *Indications for use.* Aid in control of swine dysentery. For use in swine or in swine on premises with a history of swine dysentery but where symptoms have not yet occurred.

(ii) *Animal weight.* Up to 120 pounds.

(4) *Amount per ton.* 10 grams.

(i) *Indications for use.* Increased rate of weight gain and improved feed efficiency (starter and grower Type D articles only).

(ii) *Animal weight.* Weaning to 120 pounds.

§ 588.680 Zoalene.

(a) [Reserved]

(b) *Assay limits.* Type D medicated feed article: 85 to 115 percent of labeled amount.

(c) *Special considerations.* Type D medicated feed articles for poultry containing zoalene as a sole drug, processed from Type C articles containing not more than 0.0375 percent zoalene, and conforming to the requirements of paragraph (e) of this section are not required to comply with the provisions of section 512(m) of the Federal Food, Drug, and Cosmetic Act.

(d) *Related tolerances.* See § 556.770 of this chapter.

(e) *Conditions of use.* (1) It is used in Type D medicated feed articles for chickens and turkeys as follows:

Zoalene in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004 to 0.0125 pct).	.....	Replacement chickens; development of active immunity to coccidiosis.	In type D articles only; grower type D article not to be fed to birds over 14 weeks of age; as follows—.	.....

Growing conditions	Starter type D article	Grower type D article
	Grams per ton	*Grams per ton*
Severe exposure.....	113.5 (0.0125 pct)	75.4–113.5 (0.0083 to 0.0125 pct)
Light to moderate exposure.	75.4–113.5 (0.0083 to 0.0125 pct).	36.3–75.4 (0.004 to 0.0083 pct)

Arsanilate sodium 90 (0.01 pct).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	In Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	.....
Arsanilic acid 90 (0.01 pct).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	In Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	.....

Zoalene in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As erythromycin thiocyanate; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 92.5.	1. Replacement chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmenation.	Feed for 2 d before stress and 3 to 6 d after stress; as erythromycin thiocyanate; in Type D articles only; grower Type D article not to be fed to birds over 11 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	do	2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 7 to 14 d; as erythromycin thiocyanate; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 185.	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation and development of active immunity to coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as erythromycin thiocyanate; and as sole source of organic arsenic; feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01 pct) plus penicillin 2.4 to 50.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As procaine penicillin; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	Bacitracin 100 to 500	Replacement chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); development of active immunity to coccidiosis.	As bacitracin zinc; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; feed according to subtable in item (i).	
	Chlortetracycline 100 to 200.	Replacement chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); prevention of synovitis; development of active immunity to coccidiosis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride; in Type D articles only; grower Type D article not to be fed to birds 14 of age; feed according to subtable in item (i).	
	Chlortetracycline 200.	Replacement chickens; control of synovitis; development of active immunity to coccidiosis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; feed according to subtable in item (i).	
	Eryghromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.	As erythromycin thiocyanate; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; feed according to subtable in item (i).	
	Erythromycin 92.5....	1. Replacement chickens; as an aid in the prevention of chronic respiratory disease during periods of stess; development of active immunity to coccidiosis.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; as erythromycin thiocyanate; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; feed according to subtable in item (i).	
	Erythromycin 92.5....	2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis.	Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; feed according to subtable in item (i).	
	Erythromycin 185.....	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; development of active immunity to coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; in Type D articles only (grower Type D article not to be fed to birds over 14 weeks of age), feed according to subtable in item (i).	
	Hygromycin B 8 to 12.	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	In Type D articles only; Type D article ration not to be fed to birds over 14 weeks of age; feed according to subtable in item (i).	
	Penicillin 2.4 to 50....	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.	As procaine penicillin; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; feed according to subtable in item (i).	
	Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005 pct).	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As procaine penicillin; in Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	Roxarsone 22.7 to 45.4 (0.0025 to 0.005 pct).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	In Type D articles only; grower Type D article not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
(ii) 113.5 (0.0125 pct).	.....	Broiler chickens; prevention and control of coccidiosis.	.....	.....
	Arsanilate sodium 90 (0.01 pct).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 days before slaughter; as sole source of organic arsenic.	.....
	Arsanilic acid 90 (0.01 pct).	do	do	.....
	Arsanilic acid 90 (0.01 pct) plus bacitracin 4 to 50.	do	Withdraw 5 d before slaughter, as sole source of organic arsenic, as bacitracin methylene disalicylate.	.....
	Arsanilic acid 90 (0.01 pct) plus erythromycin 4.6 to 18.5.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.	.....
	Arsanilic acid 90 (0.01 pct) plus erythromycin 92.5.	1. Broiler chickens; aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation; control of coccidiosis.	do	.....

Zoalene in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		2. Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation; aid in the prevention of infectious coryza.	do	
	Arsanilic acid 90 (0.01 pct) plus erythromycin 185.	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; as erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01 pct) plus penicillin 2.4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As procaine pencillin; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As bacitracin methylene disalicylate, or zinc bacitracin	
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 pct to 0.005 pct).	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As bacitracin methylene disalicylate, or zinc bacitracin; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 100 to 500	Broiler chickens; treatment of chronic respiratory disease (air-sac infection) blue comb (nonspecific infectious enteritis); prevention and control of coccidiosis.	As zinc bacitracin	
	Chlortetracycline 100 to 200.	Broiler chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); prevention of synovitis; prevention and control of coccidiosis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride.	
	Chlortetracycline 200.	Broiler chickens; prevention and control of coccidiosis; control of synovitis.	Not to be fed to laying chickens; as chlortetracycline hydrochloride.	
	Erythromycin 4.6 to 18.5.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As erythromycin thiocyanate	
	Erythromycin 92.5	Broiler chickens; aid in the prevention of chronic respiratory disease during period of stress; prevention and control of coccidiosis.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; as erythromycin thiocyanate.	
		2. Broiler chickens; as an aid in the prevention of infectious coryza; prevention and control of coccidiosis.	Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate.	
	Erythromycin 185	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; as erythromycin thiocyanate.	
	Hygromycin B (8 to 12).	Broiler chickens; prevention and control of coccidiosis; control of infestation of large round worms (*Ascaris galli*), cecal worms (*Heterakis gallinae*) and capillary worms (*Capillaria obsignata*).		
	Lincomycin 2	Broiler chickens; increase in rate of weight gain; improved feed efficiency; as an aid in the prevention and control of coccidiosis.	Do not feed to laying chickens; to be fed as the sole ration; as lincomycin hydrochloride monohydrate provided by No. 000009, see sec. 510.600(c) of this chapter; zoalene provided by No. 0.25700, see sec. 510.600(c) of this chapter.	
	Penicillin 2.4 to 50	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As procaine penicillin	
	Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 pct to 0.005 pct).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; as procaine penicillin.	
	Roxarsone 22.7 to 45.4 (0.0025 pct to 0.005 pct).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
(iii) 113.5 to 170.3 (0.0125 to 0.01875 pct).		Turkeys; prevention and control of coccidiosis	For turkeys grown for meat purposes only	
	Arsanilate sodium 90 (0.01 pct).	Turkeys; growth promotion and feed efficiency; improving pigmentation.	For turkeys grown for meat purposes only; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01 pct).	do	do	
	Carbarsone (not U.S.P.) 277 to 340.5 (0.025 to 0.0375 pct).	Turkeys; prevention and control of coccidiosis; aid in the prevention of blackhead.	For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected to continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Roxarsone 22.7 to 45.4 (0.0025 to 0.005 pct).	Turkeys; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	

(2) *Permitted combinations.* It may be used in accordance with provisions of this section in the combinations provided as follows:

(i) Bambermycins in accordance with § 558.95.

(ii) Roxarsone in accordance with § 558.530.

Interested persons may, on or before march 20, 1978, submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107. A copy of the inflation impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: January 9, 1978.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

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